B|BRAUN
SHARING EXPERTISE

February 12, 2021

<u>**Via Electronic and Overnight Delivery**</u>
Mark Wejkszner, P.E.
Air Quality Program Manager
Pennsylvania Department of Environmental Protection
Northeast Regional Office
2 Public Square
Wilkes-Barre, PA 18701
RA-EPNEstacktesting@pa.gov

AnnMary Bihl
PSIMS Administrator
Source Testing Section
Pennsylvania Department of Environmental Protection
Rachel Carson State Office Building
400 Market Street
Harrisburg, PA 17101
RA-EPstacktesting@pa.gov

Re: Plan Approval No. 39-00055B
Submission of Stack Test Report
B. Braun Medical Inc. Facility
901 Marcon Boulevard
<u>Allentown, Pennsylvania</u>

Dear Mr. Wejkszner and Ms. Bihl:

B. Braun Medical Inc. (B. Braun) was issued Plan Approval No. 39-00055B (the Plan Approval) on January 30, 2020. The Plan Approval authorized the installation and operation of a new control device at the facility, consisting of a Catalytic Oxidizer with Peak Shaver (Source ID C004). B. Braun commenced full operation of the control system on September 21, 2020, and performed emissions testing on December 15, 2020 according to the protocol approved by PADEP on November 30, 2020.

In accordance with Condition E.004 of the Plan Approval, please accept for review the enclosed emission test report prepared by Pace Environmental. By copy of this letter to EPA, this letter will likewise serve as submission of the results of a performance test pursuant to 40 C.F.R. Part 63, Subpart O, Ethylene Oxide Emissions Standards for Sterilization Facilities.

Please note that the emission test report contains confidential business information. This information is clearly marked. The confidential business information is process operating data that, if disclosed, would reveal production or process figures or methods that are unique to B. Braun and would adversely affect and cause substantial harm to B. Braun's competitive position by revealing trade secrets, including intellectual property rights. The information identified as confidential does not constitute emission data. As such, B. Braun requests that PADEP and EPA maintain the designation of this information as confidential and restrict the disclosure of such material consistent with Section 13.2 of the Pennsylvania Air Pollution Control Act, 35 P.S. § 4013.2, and 40 CFR Part 2, Subpart B. B. Braun is submitting both a public and a confidential copy of the test report.

Also enclosed for review is a Performance Evaluation Report prepared in accordance with 40 C.F.R. Part 63, Subpart O, Ethylene Oxide Emissions Standards for Sterilization Facilities for the continuous temperature monitoring system installed on the control device and used to demonstrate compliance with Subpart O and Plan Approval Condition E.006.

If you have any questions concerning these reports, please contact me at (610) 596-2474 or eric.geder@bbraunusa.com.

Sincerely,
B. Braun Medical Inc.

Eric Geder, CSP
EH&S Manager

cc: EPA Region 3
Director, Air Protection Division
1650 Arch Street
Philadelphia, PA 19103

PUBLIC VERSION

40 CFR 63 SUBPART O & PADEP PLAN APPROVAL COMPLIANCE EMISSIONS TEST REPORT FOR THE ANGUIL CATALYTIC OXIDIZER WITH PEAK SHAVER (SOURCE ID C004) AT B. BRAUN MEDICAL, INC. ALLENTOWN, PENNSYLVANIA

Plan Approval No. 39-00055B
Issuance Date: January 30, 2020
Primary Facility ID No.: 514477

Prepared for:

B. Braun Medical, Inc.
Attn: Mr. Eric Geder,
EHS&S Manager
901 Marcon Blvd.
Allentown, PA 18109
(610) 596-2474

Submitted to:

PADEP- Central Office
Attn: PSIMS Administrator
P.O. Box 8468
Harrisburg, PA 17105-8468
and
PADEP- NE Regional Office
Attn: Mr. Mark Wejkszner
2 Public Square
Wilkes-Barre, PA 18711-0790
and
U.S. EPA Region 3
1650 Arch Street
Philadelphia, PA 19103-2029

Prepared By:

Erica L. Bolek, QA/QC Manager
PACE Environmental
(PADEP Lab Reg ID No. 39-03352)
5260 West Coplay Road
Whitehall, PA 18052
(610) 262-3818

Test Date: December 15, 2020

Report Date: February 12, 2021

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TABLES

APPENDICES

1.0 INTRODUCTION

PACE Environmental (PACE) was retained by B. Braun Medical, Inc. (B. Braun) to perform an emissions compliance test at their facility located in Allentown, Pennsylvania. Testing was performed to determine ethylene oxide (EtO) emissions from the Catalytic Oxidizer (CatOx) with Peak Shaver (Source ID No. C004). B. Braun operates eight EtO sterilization chambers (Source ID Nos. 101 through 108) and one aeration room (Source ID No. 110). EtO emissions from these sources are controlled by Source ID No. C004.

The purpose of this test program was to demonstrate compliance with the test requirements and emission limits specified in the facility's Pennsylvania Department of Environmental Protection (PADEP) Plan Approval No. 39-00055B and 40 CFR 63 National Emission Standards for Hazardous Air Pollutants for Source Categories (NESHAP) Subpart O, "Ethylene Oxide Emissions Standards for Sterilization Facilities". Testing was performed in accordance with the approved compliance test protocol and follow up correspondence with the Department (found in Appendix A).

Three separate EtO test runs were performed simultaneously on the inlet and outlet of C004 during sterilization chamber operation to demonstrate compliance with the 99% emissions reduction requirement. Three separate 60-minute EtO test runs were performed on the outlet of C004 during aeration room operation to demonstrate compliance with the outlet only concentration-based emission limit of 1 part per million by volume, dry basis (ppmvd).

In our assessment of the results, this source is compliant with all applicable emission limits found in the facility permit.

Table 1.1 Test Results Summary

Plan Approval No.:	39-00055B		
Issuance Date:	January 30, 2020		
Primary Facility ID No.:	514477		
Source:	**Sterilization Chamber 7 (Source ID No. 107)**		
Control Device:	Catalytic Oxidizer with Peak Shaver (Source ID C004)		
Test Date:	**12/15/20**		
Tested Pollutant	**Average Test Result**	**Emission Limit**	**Compliance Status**
EtO (% emissions reduction, grams basis)	99.98%	≥99%	Compliant
Source:	**Aeration Room (Source ID No. 110)**		
Control Device:	Catalytic Oxidizer with Peak Shaver (Source ID C004)		
Test Date:	**12/15/20**		
Tested Pollutant	**Average Test Result**	**Emission Limit**	**Compliance Status**
EtO (ppmvd)	0.701 ppmvd	≤1 ppmvd	Compliant

1.0 INTRODUCTION (CONT'D)

Tables 1.2 and 1.3 below summarize the reference methods used during this test program.

Table 1.2 Test Methodology - Sterilization Chamber

Parameter	Method
	Sterilization Chamber Outlet / Oxidizer Inlet
EtO inlet loading to oxidizer	Calculated based on EtO cylinder charge weights, EtO mass percent of gas and documented temperature, pressure, and volume by B. Braun personnel.
	Oxidizer Outlet
Volumetric Flow Rate	U.S. EPA Method 1, "Sample and Velocity Traverses for Stationary Sources"
	U.S. EPA Method 2, "Determination of Stack Gas Velocity and Volumetric Flow Rate (Type S Pitot Tube)"
Oxygen & Carbon Dioxide	U.S. EPA Method 3A, "Determination of Oxygen and Carbon Dioxide Concentrations in Emissions from Stationary Sources (Instrumental Analyzer Procedure)"
Moisture	U.S. EPA Method 4, "Determination of Moisture Content in Stack Gases"
EtO	U.S. EPA Method 25A, "Determination of Total Gaseous Organic Concentration using a Flame Ionization Analyzer"

During sterilization, each test run lasted the duration of the first chamber evacuation, which is approximately 20 minutes. The duration of Runs 1, 2 and 3 were 22, 22, and 21 minutes, respectively. During each run, the moisture content was sampled for 30 minutes at a 2.0 inch of water (delta H) sampling rate to meet the method sample volume requirement of 21 dry standard cubic feet (dscf).

Table 1.3 Test Methodology- Aeration Room

Parameter	Method
	Oxidizer Outlet
Moisture	U.S. EPA Method 4, "Determination of Moisture Content in Stack Gases"
EtO	U.S. EPA Method 25A, "Determination of Total Gaseous Organic Concentration using a Flame Ionization Analyzer"

EtO outlet emissions are reported as ppmvd during both the sterilization and aeration test scenarios. EtO outlet mass emissions as pounds per hour (lb/hr) are reported during sterilization only. Emissions results during each test scenario are detailed in Tables 3.1 and 3.2.

2.0 QUALITY ASSURANCE SUMMARY

A compliance test protocol was submitted to the Department on October 14, 2020 and conditionally approved on November 25, 2020. In this protocol all sampling and analytical procedures were detailed.

Appendix A includes the conditionally approved protocol and all pertinent correspondence with PADEP.

All calibrations, QA/QC checks, and leak checks conducted during this test program were within the acceptable limits established by the U.S. EPA methods. All data supporting these findings can be found in the appendices of the report.

3.0 SUMMARY OF RESULTS

The results of the Sterilization Chamber and Aeration Room tests are detailed below in Tables 3.1 and 3.2, respectively. All results are below the permitted emission limits.

Table 3.1 Executive Summary: Sterilization Chamber

Run	1	2	3	**Average**	**Emission Limit**
Date	12/15/20	12/15/20	12/15/20		
Time	0836-0858	1310-1332	1709-1730		
Outlet Volumetric Flow Rate					
dscfm	15,727	15,663	18,129	16,506	------
Outlet Ethylene Oxide					
ppmv, dry	0.736	0.806	0.784	0.775	------
pounds/hour	0.0794	0.0865	0.0975	0.0878	------
grams	**13.4**	**14.7**	**15.8**	**14.6**	------
Inlet Ethylene Oxide					
grams	**60,973**	**64,705**	**62,336**	**62,671**	------
CatOx Efficiency					
%, EtO grams basis	**99.978**	**99.977**	**99.975**	**99.977**	**≥99%**

Table 3.2 Executive Summary: Aeration Room

Run	1	2	3	**Average**	**Emission Limit**
Date	12/15/20	12/15/20	12/15/20		
Time	1042-1142	1155-1255	1535-1635		
Ethylene Oxide Outlet					
ppmv, dry	**0.713**	**0.658**	**0.731**	**0.701**	**≤1.0**

4.0 TECHNICAL DISCUSSION

All testing was performed as detailed in the approved test protocol and agreed upon in follow up correspondence with Mr. Kenneth Kuschwara of PADEP (see Appendix A). No technical difficulties or protocol deviations were experienced during this test program.

5.0 PROCESS DESCRIPTION

B. Braun operates a medical device manufacturing facility in Allentown, PA. This facility operates a newly installed Anguil Environmental Systems, Inc. (Anguil) control device system which consists of a peak shaver and 3.0 million British thermal units per hour (MMBtu/hr) natural gas-fired catalytic oxidizer. The "Anguil System" controls EtO emissions from the eight Sterilizers and Aeration Room (Source IDs 101 – 108 and 110, collectively known as "Source Group 1" or "EtO Sterilizers"). The Anguil System control device is intended to replace the pre-existing Catalytic Oxidizer (Control Device ID C001) and Wet Scrubber Deoxx Unit (Control Device ID C002).

5.1 Sterilization Process

B. Braun manufactures medical devices for multiple health care applications. These instruments must be properly sterilized to ensure the safety of patients and health care providers, as well as to satisfy specific, rigorous standards imposed by the United States Food and Drug Administration (FDA). To accomplish these critical objectives, B. Braun implements appropriate procedures to achieve proper sterilization of the medical devices in the context of the manufacturing process at the facility.

The sterilization process utilizes EtO within the eight sterilization chambers. At the conclusion of the EtO dwell portion of the sterilization process, EtO is evacuated from the chamber using a vacuum pump that discharges to the Anguil System. From the sterilization chambers, the sterilized medical devices are taken to the Aeration Room where residual EtO is released from the sterilized devices and controlled with the Anguil System.

The peak shaver works to normalize the concentration of EtO sent to the catalytic oxidizer. The peak shaver recirculates water from a holding tank over a packed scrubber bed. The sterilizer exhaust runs countercurrent to the water and the EtO is absorbed into the water. After the sterilization cycle is finished, the EtO is stripped from the water via a fresh air source at a controlled rate and directed to the catalytic oxidizer. In the exhaust stream to the catalytic oxidizer, the peak shaver exhaust mixes with Aeration Room air in the interconnecting ductwork.

The catalytic oxidizer is comprised of three total CARULITE 500 pelletized catalyst beds. The catalyst bed temperatures are monitored using Type K thermocouples in accordance with 40 CFR §63.364(c) to ensure compliance with the manufacturer's minimum temperature recommendations as required by 40 CFR §63.363(b)(3). A performance evaluation of the temperature monitor was performed during the performance test as required by 40 CFR §63.8(e).

5.2 Operating Conditions during Testing

The following two sections describe the actual process operations during the sterilization chamber test and the aeration room test.

Initial operational compliance of the control device has been demonstrated by ensuring that the temperature in the oxidation chamber is maintained at a temperature above the minimum oxidation temperature recommended by the catalyst manufacturer while the catalytic oxidizer system is operating and controlling EtO emissions. During the stack test, the oxidizer inlet temperature was operated at a set point of 154.4°C/310°F, in order to ensure sufficient margin above the minimum inlet temperature recommended by the catalyst manufacturer (150°C/302°F). According to Plan Approval Condition E.III.6.c, ongoing compliance will be demonstrated by maintaining an inlet temperature above the minimum oxidation temperature achieved during the successful performance test (152.8°C/307°F).

All process data collected during the test program and forwarded to PACE is provided in Appendix G. Tables 5.1 and 5.2 summarize the process parameters recorded during each test scenario by B. Braun personnel.

5.2.1 Sterilization Chambers

Testing was performed on an empty sterilization chamber, charged with a typical amount of EtO, for the duration of the first evacuation under normal operating conditions (i.e., sterilization pressure and temperature) as required by 40 CFR §63.365(b)(1).

Sterilization Chamber 7 (Source ID No. 107) was used for compliance demonstration since it is the largest chamber with a total volume of 3,600 cubic feet and, when used in conjunction with sterilization process cycle #1, provides the highest loading of EtO to the control device that is possible under normal operating conditions. The chamber was charged with approximately [redacted] pounds of EtO. The first evacuation of EtO from the chamber lasted approximately 20 minutes. Three separate test runs were conducted during three separate first evacuation periods.

The amount of EtO loaded into the sterilizer was determined by weighing the EtO gas cylinder used to charge the sterilizer before and after charging. At the completion of the first evacuation, facility personnel recorded the chamber temperature, pressure and volume using pre-existing equipment.

The inlet and outlet temperatures (°F) for the catalyst bed were recorded at 1-minute intervals by facility personnel to document proper operation of the control device during testing.

Table 5.1 Process Parameter Summary- Sterilization Chamber

Run Number	1	2	3	Averages
Test Date	12/15/20	12/15/20	12/15/20	
Test Time	0836-0858	1310-1332	1709-1730	
Process/Control Device Data Summary				
EtO gas charged to chamber (lbs)	[redacted]	[redacted]	[redacted]	[redacted]
Initial chamber pressure (psia)	[redacted]	[redacted]	[redacted]	[redacted]
Initial chamber temperature (°C)	[redacted]	[redacted]	[redacted]	[redacted]
Final chamber pressure	[redacted]	[redacted]	[redacted]	[redacted]
Final chamber temperature	[redacted]	[redacted]	[redacted]	[redacted]
Minimum Inlet temperature during performance test (°F)	307[1]			N/A
Average CatOx Inlet temperature (°F)	313.4	313.3	312.9	313.2
Average CatOx Outlet temperature (°F)	349.9	353.1	352.6	351.9

[1]Note the minimum temperature during sterilization was 308°F; however, the overall minimum during the entire performance test was 307°F.

5.2.2 Aeration Room

During the aeration room tests, the room was loaded with the maximum number of sterilized equipment B. Braun could load into the room. The residual EtO from this sterilized equipment was released in the aeration room and vented to the oxidizer.

The inlet and outlet temperatures (°F) for the catalyst bed were recorded at 1-minute intervals by facility personnel to document proper operation of the control device during testing.

Table 5.2 Process Parameter Summary- Aeration Room

Run Number	1	2	3	Averages
Test Date	12/15/20	12/15/20	12/15/20	
Test Time	1042-1142	1155-1255	1535-1635	
Process/Control Device Data Summary				
Minimum Inlet temperature during performance test (°F)	307			N/A
Average CatOx Inlet temperature (°F)	309.7	309.8	309.8	309.8
Average CatOx Outlet temperature (°F)	331.6	323.2	329.5	328.1

6.0 PERSONNEL AND CERTIFICATIONS

Field Sampling on this Project was performed by:

Brandon Gallagher, John Donnelly and Larkin Recke

Calculations and Report Preparation were performed by:

Erica L. Bolek

CERTIFICATION STATEMENT:

I certify that "to the best of my knowledge" this source test report has been checked for completeness, and that the results presented herein are accurate, error-free, legible, and representative of the actual emissions measured during testing.

Submitted by:

Erica L. Bolek
QA/QC Manager

Reviewed by:

John Donnelly
Partner

Project/Field Personnel:

Brandon Gallagher
Project Manager

RESPONSIBLE-OFFICIAL CERTIFICATION

The below certification is for the compliance emissions test performed on the outlet stack of the Catalytic Oxidizer and Peak Shaver (C004) while testing both Sterilization Chamber and Aeration Room operating scenarios on December 15, 2020 at B. Braun Medical, Inc. in Allentown, Pennsylvania.

I certify that "to the best of my knowledge" this source test report has been checked for completeness, and that the results presented herein are accurate, error-free, legible, and representative of the actual emissions measured during testing.

Rex R. Boland
Signature

Rex Boland
Name

V.P. & G.M.
Title

2-11-21
Date

7.0 SAMPLE LOCATION

EPA METHOD 1

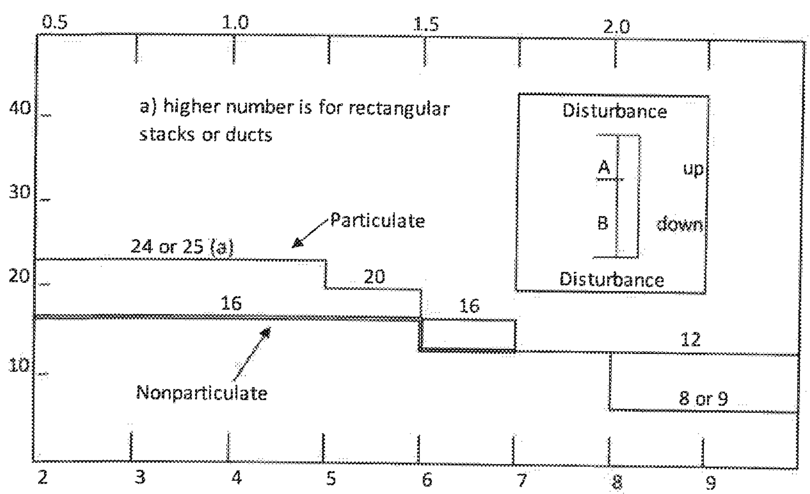
Sample and Velocity Traverses for Stationary Sources

Customer	B. Braun
Facility	Medical equipment & sterilization
City, State	Allentown, PA
Test Date	12/15/20
Test Location	CatOx Outlet
Diameter of Stack	29.5 inches

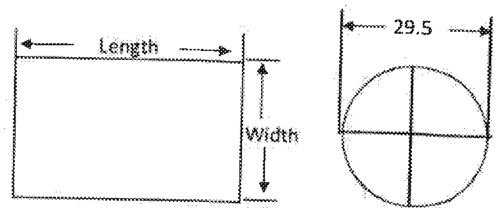
Diameters Upstream of Disturbance (A)	8.1
Diameters Downstream of Disturbance (B)	14.2
Total No. of Traverse Points Required	16
Number of Ports	2
Traverse Points per Port	8
Traverse (Horizontal or Vertical)	V

MINIMUM NUMBER OF TRAVERSE POINTS FOR PARTICULATE AND NONPARTICULATE TRAVERSES

Duct Diameters Upstream from flow disturbances (Disturbance A)



Duct Diameters Downstream from flow disturbances (Disturbance B)



Deq = $\frac{2LW}{L+W}$ = ________

CROSS-SECTIONAL LAYOUT FOR RECTANGULAR STACKS	
Total Travese Points	Matrix
9	3x3
12	4x3
16	4x4
20	5x4
25	5x5

LOCATION OF TRAVERSE POINTS IN CIRCULAR STACKS

Point Number On A Diameter	(Percent of stack diameter from inside wall to traverse point) Number of Traverse Points on a Diameter				
	4	6	8	10	12
1	6.7	4.4	3.2	2.6	2.1
2	25.0	14.6	10.5	8.2	6.7
3	75.0	29.6	19.4	14.6	11.8
4	93.3	70.4	32.3	22.6	17.7
5		85.4	67.7	34.2	25.0
6		95.6	80.6	65.8	35.6
7			89.5	77.4	64.4
8			96.8	85.4	75.0
9				91.8	82.3
10				97.4	88.2
11					93.3
12					97.9

TRAVERSE POINT LOCATIONS

Number	Distance from Wall (inches)	Port Depth (inches)	Total Distance (inches)
1	0.9		0.9
2	3.1		3.1
3	5.7		5.7
4	9.5		9.5
5	20.0		20.0
6	23.8		23.8
7*	26.4		26.4
8	28.6		28.6
9			
10			
11			
12			

*Note: A complete set of flow traverses was measured prior to testing during normal process operations. The average differential pressure (Δp) reading was calculated, and the pitot tube was secured in the stack at the traverse point with the reading closest to the average Δp value (Traverse Pt #7). The Δp and stack temperature was recorded at one-minute intervals during each run. The pitot tube was monitored frequently to ensure proper alignment within the stack.

8.0 CYCLONIC FLOW

Location:
CatOx Outlet

Point	CYCLONIC FLOW Rotation Angle, Degrees Port A	 Port B
1	2	4
2	2	3
3	0	1
4	0	0
5	0	0
6	0	0
7	0	1
8	0	1
Average	0.5	1.3
Overall Average	**0.9**	

Note: The absence of cyclonic flow is verified with an average angle less than 20 degrees.

APPENDIX A

PROTOCOL CORRESPONDENCE & APPROVED TEST PROTOCOL

From:	Kuschwara, Kenneth <kkuschwara@pa.gov>
Sent:	Monday, November 30, 2020 3:05 PM
To:	Eric Geder
Cc:	Kempa, Raymond; Patel, Shailesh; Erica Bolek
Subject:	RE: [External] RE: B. Braun Med Inc., Allentown Facility Baseline Test Protocol Review Completed - See Letter, Attached

Eric,

Your responses are acceptable for the upcoming performance test.

Have a great evening.

Kenneth Kuschwara, M.S. | Environmental Chemist 2
Department of Environmental Protection
Rachel Carson State Office Building
400 Market Street | Harrisburg, PA 17105-8468
Phone: 484.250.7517 | Fax: 717.772.2303
www.dep.pa.gov

SOURCE TESTING FAQs
https://www.dep.pa.gov/Business/Air/BAQ/BusinessTopics/SourceTesting/Pages/default.aspx

From: Eric Geder <eric.geder@bbraunusa.com>
Sent: Monday, November 30, 2020 2:51 PM
To: Kuschwara, Kenneth <kkuschwara@pa.gov>
Cc: Kempa, Raymond <rkempa@pa.gov>; Patel, Shailesh <spatel@pa.gov>; Erica Bolek <erica@paceenvironmental.com>
Subject: [External] RE: B. Braun Med Inc., Allentown Facility Baseline Test Protocol Review Completed - See Letter, Attached

Kenneth,

We appreciate the timely review of the submitted test protocol for the B. Braun (Plan Approval #39-00055B) facility. Please see the attached response to the concerns presented in the letter sent on November 25th, 2020.
A copy of this letter was also send overnight via UPS.

Regards,
Eric

Eric Geder, CSP
EHS&S Manager

B|Braun Medical, Inc.
Phone: 610-596-2474
Cell: 484-387-9254
Email: eric.geder@bbraunusa.com

B BRAUN
SHARING EXPERTISE

From: Kuschwara, Kenneth [mailto:kkuschwara@pa.gov]
Sent: Wednesday, November 25, 2020 6:55 AM
To: Eric Geder <eric.geder@bbraunusa.com>; Erica Bolek <erica@paceenvironmental.com>
Cc: Kempa, Raymond <rkempa@pa.gov>; Patel, Shailesh <spatel@pa.gov>
Subject: B. Braun Med Inc., Allentown Facility Baseline Test Protocol Review Completed - See Letter, Attached

Eric and Erica,

The B. Braun Med Inc., Allentown Facility baseline test protocol review is completed - see letter, attached.

FYI – I will be out of the office beginning November 25th and return on November 30th. Have a great holiday.

Kenneth Kuschwara, M.S. | Environmental Chemist 2
Department of Environmental Protection
Rachel Carson State Office Building
400 Market Street | Harrisburg, PA 17105-8468
Phone: 484.250.7517 | Fax: 717.772.2303
www.dep.pa.gov

SOURCE TESTING FAQs
https://www.dep.pa.gov/Business/Air/BAQ/BusinessTopics/SourceTesting/Pages/default.aspx

B BRAUN
SHARING EXPERTISE

November 30, 2020

Mr. Kenneth Kushwara
Environmental Chemist II
Source Testing Section
Pennsylvania Department of Environmental Protection
Rachel Carson State Office Building
400 Market Street
Harrisburg, PA 17101

Re: B. Braun Medical Inc.
Plan Approval No. 39-00055B

Dear Mr. Kuschwara,

Thank you for your timely review of the Test Protocol submitted for the Catalytic Oxidizer with Peak Shaver (Source ID: C004), used to control the emissions from the Sterilizers (130, 3700, 1200, 1250, and 1000 cu. ft.) (Source IDs: 101-108) and Aeration Room (Source ID: 110) at the B. Braun Medical, Inc. ("B. Braun") Facility in Hanover Twp., Lehigh County pursuant to Plan Approval No. 39-00055B.

Your November 23, 2020 letter indicated that the Test Protocol was unacceptable to the PADEP unless certain conditions listed therein are met. This letter will respond to the conditions listed in your letter, and requests confirmation that B. Braun's Test Protocol is acceptable based on the additional information provided herein. Please find B. Braun's responses below, following the conditions set forth in your letter:

1. Although the protocol specifies that the sterilizer chamber evacuation time is approximately 20 minutes, a performance test should consist of three 1-hour test runs. Increasing the number of proposed (3) chamber evacuations would be an acceptable option to increase total testing time for the sterilizer performance test.

Response: While B. Braun acknowledges that a performance test typically consists of three 1-hour runs, this condition is inconsistent with the 40 CFR Subpart O regulations and Plan Approval conditions governing the performance testing procedures. 40 CFR 63.365(b) and Plan Approval Condition E.II.5 describe the procedures to be used "to determine the efficiency of all types of control devices used to comply with 63.362(c), sterilization chamber vent standard." 40 CFR 63.365(b)(1), and Plan Approval Conditions E.II.5(b) and E.II.5(b)(1), all state that "These procedures shall be performed on an empty sterilization chamber, charged with a typical amount of ethylene oxide, **for the duration of the first evacuation under normal operating conditions (i.e. sterilization pressure and temperature).** [emphasis added]."

40 CFR 63.365(b)(1)(vi) and Plan Approval Condition E.II.5(b)(1)(vi) state that the performance test procedures referenced above shall be repeated three times, and the arithmetic average percent efficiency of the three runs shall determine the overall efficiency of the control device. Therefore, requiring additional evacuations would be inconsistent with Subpart O and Plan Approval requirements.

The general requirements for performance testing described in 40 CFR 63.7 do not require that the test runs be 1-hour in duration. In fact, 40 CFR 63.7(e)(3) states that "Each run shall be conducted for the time and under the conditions specific in the relevant standard." Likewise, the sampling and analytical methods described in the protocol do not specify a run duration.

Furthermore, increasing the number of sterilization chamber evacuations beyond what is required by the federal emission standard and Plan Approval conditions will add significantly to the cost and operational downtime required to carry out the performance test. Because of the wide flammable and explosive ranges of ethylene oxide concentrations, B. Braun's sterilization procedures are highly automated, and require multiple consecutive chamber evacuation purges using nitrogen and air to ensure safe operations. Because of this, it is not possible to perform multiple, consecutive evacuations of a chamber fully charged with ethylene oxide. Although the first evacuation of ethylene oxide takes approximately 20 minutes, the total sterilization process cycle time is approximately 5 hours start-to-start, and cannot be modified for safety reasons (and because such modification would not reflect the 'normal' operating conditions required for testing). Therefore, adding additional sterilization cycles to meet the 1-hour condition from your letter would add *at least* 30 hours of additional downtime to the sterilization process, at a time when B. Braun's medical device products and sterilization services are in great need.

For purposes of demonstrating compliance with the aeration room vent standard, and as described in the Test Protocol, B. Braun will perform three 1-hour test runs. However, for demonstrating compliance with the sterilization chamber vent standard, B. Braun respectfully requests that the PADEP allow it to utilize an approximately 20-minute test run, for consistency with representative facility operations and with the performance test procedures described in the federal emission standard, Plan Approval, and Test Protocol.

2. To the extent possible, the aeration room process should aerate C_2H_4O at maximum normal operating conditions (MNOC), which is worst-case conditions for VOC concentration emissions during the aeration test.

B. Braun will make every reasonable effort to ensure that the aeration room is as full of product as possible on the date of the performance test. While the amount of product in the aeration room at any given time is highly dependent on customer demand and order fulfillment, in all circumstances ethylene oxide concentrations from the aeration room vent are expected to be far lower than those from the sterilization chamber vent during the first evacuation.

3. For each sterilizer and aeration room test, a process summary table, displaying individual run and test average columns, and including all sources, parameters, and units, must be included in the test report. Include applicable pressures, temperatures, C_2H_4O usage, settings, rates, etc. to show actual operating conditions during the tests. Also include applicable process parameters for both the peak shaver and catalytic oxidizer processes (oxidizer parameters must include catalyst inlet/outlet temperatures and catalyst ΔP (if possible)). Any manually recorded process parameter raw data values shall be recorded at 15-minute intervals during each test run, where possible, and included in the test report. Also, include all electronic raw data sheets in the test report.

B. Braun will provide all applicable and possible process parameters and operating conditions in the test report, in both summary and electronic formats.

4. 40 CFR 63 Subpart O requires establishing a catalytic oxidizer minimum temperature operating limit during this initial performance test. However, an oxidizer catalyst inlet target (actual) temperature has not been proposed in the protocol. A proposed target temperature must be approved by the Northeast Regional Office prior to the performance test date.

B. Braun has been in contact with the Northeast Regional Office to discuss the catalytic oxidizer inlet temperature during performance testing. The recommended minimum inlet temperature identified by the catalyst manufacturer is 302°F. For performance testing, B. Braun has proposed a set point temperature of 310°F in order to provide a sufficient margin of compliance and to demonstrate compliance with the destruction efficiency and/or outlet concentration standard.

5. For EPA Method 25A, the VOC analyzer sampling system components must be heated to 350°F minimum to prevent condensation of VOCs.

According to the National Institute of Standards and Technology (NIST) Chemistry WebBook, ethylene oxide (the only VOC being evaluated during this performance test) has a boiling point of approximately 51°F. For this performance test, B. Braun proposes to heat the sampling system components to 250°F to prevent condensation of ethylene oxide.

Thank you for your consideration of this information. Please also allow this letter to confirm that performance testing will take place on December 15, 2020, commencing at approximately 8:00 a.m. This notice is made in accordance with Condition E.004(3) of the Plan Approval, which requires at least fifteen (15) days prior notification of the date and time of testing.

If you have any questions concerning this notification, please contact me at (610) 596-2474 or eric.geder@bbraunusa.com.

Sincerely,
B. Braun Medical Inc.

Eric Geder, CSP
EHS&S Manager

cc: Shailesh Patel, PADEP

November 23, 2020

Mr. Eric Geder
EHS&S Manager
B. Braun Medical, Inc.
901 Marcon Blvd.
Allentown, PA 18109

Re: 40 CFR 63 Subpart O Catalytic Oxidizer/Peak Shaver Baseline Test Protocol Review
B. Braun Med Inc.
Allentown Facility, Hanover Twp., Lehigh County

Dear Mr. Geder:

On October 14, 2020, the Department of Environmental Protection (DEP) received a pre-test protocol for the baseline testing to determine the VOC (as ethylene oxide; C_2H_4O) emissions and destruction efficiency (DE) from the Catalytic Oxidizer With Peak Shaver (Source ID: C004), used to control the emissions from the Sterilizers (130, 3700, 1200, 1250, and 1000 cu. ft.) (Source IDs: 101-108) and Aeration Room (Source ID: 110) at the Allentown Facility in Hanover Twp., Lehigh County.

The protocol is unacceptable to the DEP, unless all of the following conditions are met:

1. Although the protocol specifies that the sterilizer chamber evacuation time is approximately 20 minutes, a performance test should consist of three 1-hour test runs. Increasing the number of proposed (3) chamber evacuations would be an acceptable option to increase total testing time for the sterilizer performance test.
2. To the extent possible, the aeration room process should aerate C_2H_4O at maximum normal operating conditions (MNOC), which is worst-case conditions for VOC concentration emissions during the aeration test.
3. For each sterilizer and aeration room test, a process summary table, displaying individual run and test average columns, and including all sources, parameters, and units, must be included in the test report. Include applicable pressures, temperatures, C_2H_4O usage, settings, rates, etc. to show actual operating conditions during the tests. Also include applicable process parameters for both the peak shaver and catalytic oxidizer processes (oxidizer parameters must include catalyst inlet/outlet temperatures and catalyst ΔP (if possible)). Any manually recorded process parameter raw data values shall be recorded at 15-minute intervals during each test run, where possible, and included in the test report. Also, include all electronic raw data sheets in the test report.
4. 40 CFR 63 Subpart O requires establishing a catalytic oxidizer minimum temperature operating limit during this initial performance test. However, an oxidizer catalyst inlet target (actual) temperature has not been proposed in the protocol. A proposed target temperature must be approved by the Northeast Regional Office prior to the performance test date.

5. For EPA Method 25A, the VOC analyzer sampling system components must be heated to 350°F minimum to prevent condensation of VOCs.

The test report must contain the DEP laboratory registration ID for any company, engaged in the testing or analysis of environmental samples.

Acceptance of all testing is contingent upon the review of, and conformance to, the information in the FAQs, posted on the Source Testing Section's external website (https://www.dep.pa.gov/Business/Air/BAQ/BusinessTopics/SourceTesting/Pages/default.aspx); otherwise, there may be adverse consequences, including the potential rejection of affected test data, which may result in enforcement action.

It is my understanding that the testing will be conducted on December 15, 2020. Please notify the Northeast Regional Office and me at least thirty calendar days, or more if specified by the plan approval, prior to testing so that someone may be present to observe. Failure to do so could result in a rejection of the test results. Final acceptance of the test results is contingent upon fulfillment of all of the applicable requirements specified in Title 25, Chapter 139 of the PA Code; Plan Approval #39-00055B; 40 CFR 63 Subpart O; and the DEP's Source Testing Manual (Revision 3.3; November 2000). If there are any questions regarding this matter, please contact me at your convenience at kkuschwara@pa.gov or (484) 250-7517.

Sincerely,

Kenneth Kuschwara, M.S.
Environmental Chemist 2
Source Testing Section
Division of Source Testing and Monitoring

cc: Ms. Erica L. Bolek
QA/QC Manager
PACE Environmental
5260 West Coplay Road
Whitehall, PA 18052

Mr. Shailesh Patel, Air Quality Program, Northeast Regional Office
Reading File, Source Testing Section

RPS:KMK:kmk

40 CFR 63 SUBPART O & PADEP PLAN APPROVAL COMPLIANCE EMISSIONS TEST PROTOCOL FOR THE ANGUIL CATALYTIC OXIDIZER WITH PEAK SHAVER (SOURCE ID C004) AT B. BRAUN MEDICAL, INC. ALLENTOWN, PA

Plan Approval No. 39-00055B
Issuance Date: January 30, 2020
Primary Facility ID No. 514477

Prepared for:

B. Braun Medical, Inc.
Attn: Mr. Eric Geder
901 Marcon Blvd.
Allentown, PA 18109

Submitted to:

Pennsylvania Department of Environmental Protection- Central Office
Attn: PSIMS Administrator
P.O. Box 8468
Harrisburg, PA 17105-8468
and
Pennsylvania Department of Environmental Protection-Northeast Office
Attn: Mr. Mark Wejkszner
2 Public Square
Wilkes-Barre, PA 18701
and
U.S. EPA Region 3
1650 Arch Street
Philadelphia, PA 19103

Prepared By:

Erica L. Bolek
PACE Environmental
5260 West Coplay Road
Whitehall, PA 18052
PADEP Lab Reg ID No.: 39-03352

Protocol Submittal Date: October 14, 2020

Proposed Test Date: December 15, 2020

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TABLES & FIGURES

APPENDICES

1.0 INTRODUCTION

PACE Environmental (PACE) has been retained by B. Braun Medical, Inc. (B. Braun) to provide sampling support in conducting emissions testing on the Catalytic Oxidizer (CatOx) with Peak Shaver (Source ID No. C004) located at their facility in Allentown, Pennsylvania. B. Braun operates eight ethylene oxide (EtO) sterilization chambers (Source ID Nos. 101 through 108) and one aeration room (Source ID No. 110). EtO emissions from these sources are controlled by Source ID No. C004.

The purpose of this test program is to demonstrate compliance with the test requirements and emission limits specified in the facility's Pennsylvania Department of Environmental Protection (PADEP) Plan Approval No. 39-00055B and 40 CFR 63 National Emission Standards for Hazardous Air Pollutants for Source Categories (NESHAP) Subpart O, "Ethylene Oxide Emissions Standards for Sterilization Facilities".

The facility is a source using 10 tons as defined in NESHAP Subpart O §63.361. This test protocol provides sampling and analytical procedures for testing the sterilization chambers and aeration room using PADEP and the United States Environmental Protection Agency (U.S. EPA) methodology.

Three separate EtO test runs will be performed by simultaneously evaluating the inlet and outlet conditions of C004 during sterilization chamber operation to determine compliance with the 99% emissions reduction requirement.

For the aeration room, EtO emissions compliance can be demonstrated by using the outlet only concentration-based emission limit of 1 part per million by volume, dry basis (ppmvd) or 99% emissions reduction. Compliance will be demonstrated using the outlet only emission limit.

PACE will perform the on-site sampling and will prepare the final compliance report, which will include the test results, calibrations, and all supporting field data and calculations to arrive at the reported results.

Table 1.1 below summarizes the proposed test schedule. **We have tentatively scheduled the test to be performed December 15, 2020.**

Table 1.1 Proposed Test Schedule

Day	Tentative Date	Activity
1	12/14/20	Travel/Set Up
2	12/15/20	Test sterilization chambers, then test aeration room, then remove equipment

1.1 Contact Information

B. Braun:

Contact Name:	Eric Geder
Phone:	(610) 596-2474
Email:	eric.geder@bbraunusa.com
Address:	**901 Marcon Blvd.** **Allentown, PA 18109**

Testing Contractor:

Contact Name:	Erica L. Bolek
Company Name:	PACE Environmental
Address:	5260 West Coplay Road Whitehall, PA 18052
Office Phone:	(610) 262-3818
Email:	erica@paceenvironmental.com

1.2 Permit Information

Plan Approval No.:	39-00055B
Permit Issuance Date:	January 30, 2020
Primary Facility ID No.:	514477

1.3 Source Information

Source ID Name:	Catalytic Oxidizer with Peak Shaver
Source ID No.:	C004
Regulation:	40 CFR 63 Subpart O and the facility's Plan Approval

1.4 Plant Safety Requirements

All personnel should wear hearing protection, safety shoes, safety glasses with side shields and a hard hat. During the COVID-19 pandemic, entry into the facility will require temperature screening, completion of self-declaration and issuance of a mask which needs to be worn at all times while at the facility.

2.0 SOURCE DESCRIPTION

B. Braun operates a medical instrument apparatus manufacturing facility in Allentown, PA. This facility operates a newly installed Anguil Environmental Systems, Inc. (Anguil) control device system which consists of a peak shaver and 3.0 million British thermal units per hour (MMBtu/hr) natural gas-fired catalytic oxidizer. The "Anguil System" controls EtO emissions from the eight Sterilizers and Aeration Room (Source IDs 101 – 108 and 110, collectively known as "Source Group 1" or "EtO Sterilizers"). The Anguil System control device is intended to replace the pre-existing Catalytic Oxidizer (Control Device ID C001) and Wet Scrubber Deoxx Unit (Control Device ID C002).

2.1 Sterilization Process

B. Braun manufactures medical instruments for multiple health care applications. These instruments must be properly sterilized to ensure the safety of patients and health care providers, as well as to satisfy specific, rigorous standards imposed by the United States Food and Drug Administration (FDA). To accomplish these critical objectives, B. Braun implements appropriate procedures to achieve proper sterilization of the medical instruments in the context of the manufacturing process at the facility.

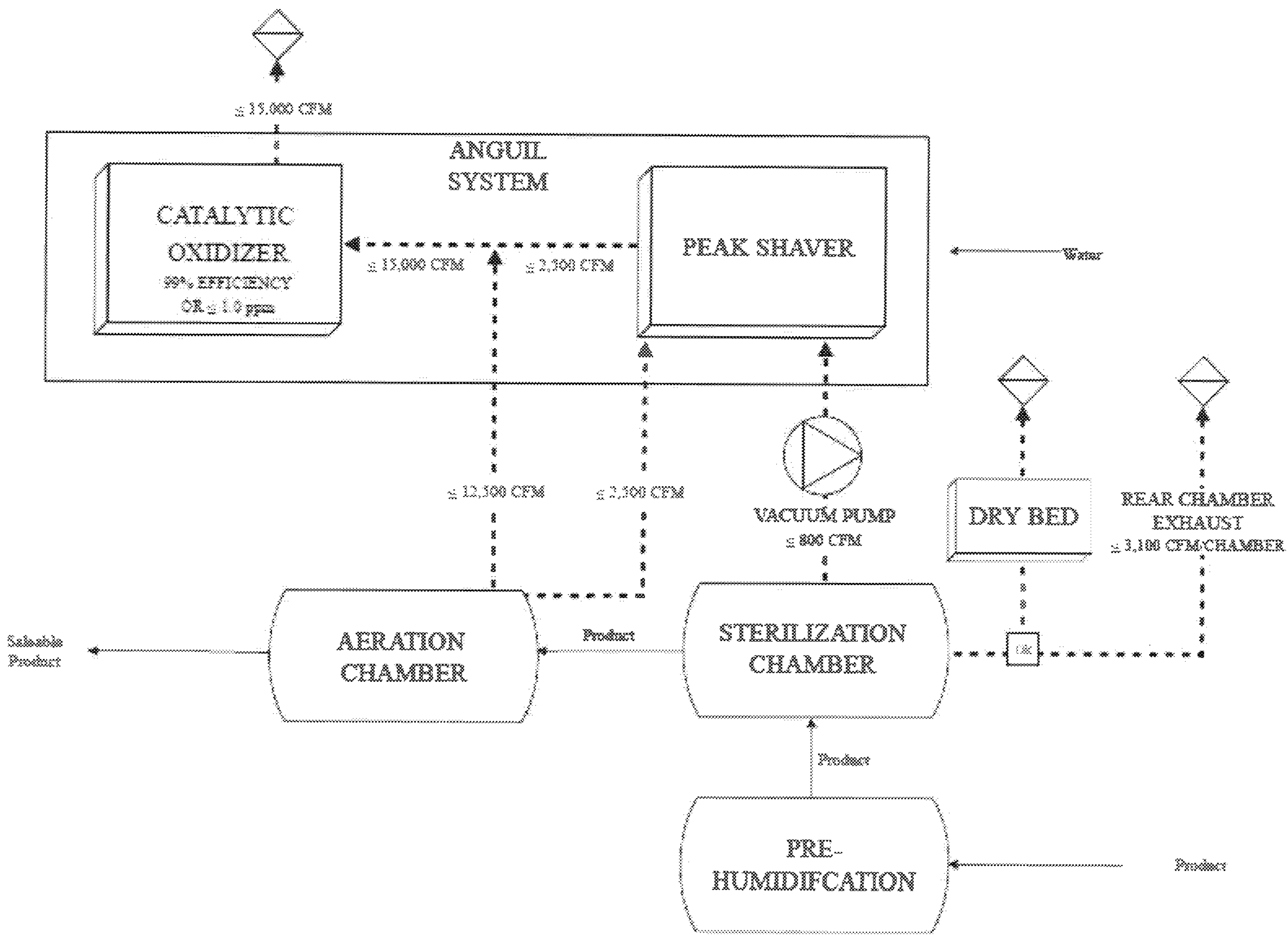
The sterilization process utilizes EtO within the eight sterilization chambers. At the conclusion of the sterilization process, EtO is evacuated from the chamber using a vacuum pump that discharges to the Anguil System. From the sterilization chambers, the sterilized instruments are taken to the Aeration Room where residual EtO is released from the sterilized instruments and controlled with the Anguil System.

The peak shaver works to normalize the concentration of EtO sent to the catalytic oxidizer. The peak shaver recirculates water from a holding tank over a packed scrubber bed. The sterilizer exhaust runs countercurrent to the water and the EtO is absorbed into the water. After the sterilization cycle is finished, the EtO is stripped from the water via a fresh air source at a controlled rate and directed to the catalytic oxidizer. In the exhaust stream to the catalytic oxidizer, the peak shaver exhaust mixes with Aeration Room air in the interconnecting ductwork.

The catalytic oxidizer is comprised of three total CARULITE 500 pelletized catalyst beds. The catalyst bed temperatures are monitored using Type K thermocouples in accordance with 40 CFR §63.364(c) to ensure compliance with the manufacturer's minimum temperature recommendations as required by 40 CFR §63.363(b)(3). A performance evaluation of the temperature monitors will be performed during the performance test as required by 40 CFR §63.8(e).

A process flow diagram is provided in Figure 2.1 on the following page.

Figure 2.1 Process Flow Diagram



2.2 Proposed Operating Conditions during Testing

The following two sections describe the intended process operations during the sterilization chamber test and the aeration room test.

2.2.1 Sterilization Chambers

Compliance testing will be performed on an empty sterilization chamber, charged with a typical amount of EtO, for the duration of the first evacuation under normal operating conditions (i.e., sterilization pressure and temperature) as required by 40 CFR §63.365(b)(1).

The facility intends to use Sterilization Chamber 7 (Source ID No. 107) for compliance demonstration. It is the largest chamber with a total volume of 3,700 cubic feet and, when used in conjunction with sterilization process cycle #1, will provide the highest loading of EtO to the control device that is possible under normal operating conditions. The chamber will be charged with approximately [redacted] pounds of EtO since the facility has identified this as being the standard loading amount necessary to run sterilization process cycle #1 in chamber #7. The first evacuation of EtO from the chamber typically lasts approximately 20 minutes. Three separate test runs covering the entire duration of the first evacuation will be performed.

The amount of EtO loaded into the sterilizer will be determined by weighing the EtO gas cylinder used to charge the sterilizer before and after charging. The weights will be recorded to the nearest 45 grams (0.1 lb). The total mass of gas charged will be multiplied by the weight percent of EtO present in the gas. At the completion of the first evacuation, facility personnel will record the chamber temperature, pressure and volume using pre-existing equipment. The facility will provide PACE with this data. The calibration gas certificate of the EtO cylinder used to charge the sterilization chamber will be included in the test report.

PACE will use the information provided by B. Braun to calculate the amount of EtO charged in the sterilizer (W_c), the residual mass of EtO in the sterilizer (W_r) and the total mass of EtO at the inlet to the control device (W_i) using the equations provided in 40 CFR §63.365(b)(1)(i)(A), §63.365(b)(1)(ii) & §63.365(b)(1)(iii), respectively.

The inlet and outlet temperatures (°F) for the catalyst bed will be recorded at 15-minute intervals (or more frequently if possible) by facility personnel to document proper operation of the control device during testing.

2.2.2 Aeration Room

During the aeration room tests, the room will be loaded with the typical amount of medical equipment B. Braun would load into the room. The residual EtO from this sterilized equipment is released in the aeration room and vented to the oxidizer.

The inlet and outlet temperatures (°F) for the catalyst bed will be recorded at 15-minute intervals (or more frequently if possible) by facility personnel to document proper operation of the control device during testing.

3.0 TEST METHODOLOGY

The test program approach involves conducting a series of three test runs on both the sterilization chamber and aeration room for EtO emissions control using EPA Reference Methods. As previously noted, for the aeration room test, compliance will be demonstrated with the outlet only concentration-based emission limit. The outlet analyzer will be calibrated using EtO calibration standards as required by 40 CFR §63.365(c)(2).

This testing will be conducted over the course of one test day. The proposed measurement parameters, associated test methods, and test duration are summarized in Tables 3.1 and 3.2 below.

Table 3.1 Test Methodology - Sterilization Chamber[1]

Parameter	Method	Number of Runs & Duration[2]
Sterilization Chamber Outlet / Oxidizer Inlet		
EtO inlet loading to oxidizer	Calculated based on EtO cylinder charge weights, EtO mass percent of gas and documented temperature, pressure, and volume by B. Braun personnel.	3 ~20-minute runs
Oxidizer Outlet		
Volumetric Flow Rate	U.S. EPA Method 1, "Sample and Velocity Traverses for Stationary Sources"	Measurements taken in 1-minute intervals
	U.S. EPA Method 2, "Determination of Stack Gas Velocity and Volumetric Flow Rate (Type S Pitot Tube)"	
Oxygen & Carbon Dioxide	U.S. EPA Method 3A, "Determination of Oxygen and Carbon Dioxide Concentrations in Emissions from Stationary Sources (Instrumental Analyzer Procedure)"	3 ~20-minute runs
Moisture	U.S. EPA Method 4, "Determination of Moisture Content in Stack Gases"	3 30-minute[3] runs
EtO	U.S. EPA Method 25A, "Determination of Total Gaseous Organic Concentration using a Flame Ionization Analyzer"	3 ~20-minute runs

[1]*The proposed methodology will be used to demonstrate compliance with the emission standards specified in 40 CFR §63.362(c).*
[2]*Test runs will last the duration of the first chamber evacuation, which is approximately 20 minutes.*
[3]*Moisture sampling time will most likely extend slightly beyond the length of the first evacuation to meet the method sample volume requirement of 21 dscf.*

3.0 TEST METHODOLOGY (CONT'D)

Table 3.2 Test Methodology- Aeration Room[1]

Parameter	Method	Number of Runs & Duration
	Oxidizer Outlet	
Moisture	U.S. EPA Method 4, "Determination of Moisture Content in Stack Gases"	3 60-minute runs
EtO	U.S. EPA Method 25A, "Determination of Total Gaseous Organic Concentration using a Flame Ionization Analyzer"	3 60-minute runs

[1]The proposed methodology will be used to demonstrate compliance with the emission standards specified in 40 CFR §63.362(d).

EtO outlet emissions will be reported as parts per million dry volume (ppmvd) during both the sterilization and aeration test scenarios. EtO outlet mass emissions as pounds per hour (lb/hr) will be reported during sterilization. The average of the three valid test runs will be used for compliance demonstration. Emission limits and proposed operating ranges are listed in Table 3.3 below.

Table 3.3 EtO Emission Limits & Operating Ranges

Source	Emission Limits	Expected In-Stack Emissions	Proposed Outlet Operating Span
Sterilization Chamber	≥99% emissions reduction	<1 ppm EtO	0-10 ppm as EtO
Aeration Room[1]	≤1 ppmvd **OR** ≥99% emissions reduction	<1 ppm EtO	0-10 ppm as EtO

[1]Compliance demonstration will be demonstrated using the concentration-based outlet emission limit.

Please note that the Subpart allows for sampling and analysis of EtO utilizing either Method 18 or 25A. PACE was unable to obtain a laboratory that could analyze via Method 18 at a low enough detection limit to demonstrate compliance with the emission limit of 1 ppm. Utilizing a Method 25A flame ionization analyzer (FIA) calibrated on a 10 ppm as EtO span provides a detection limit of 0.1 ppm, which is low enough to quantify EtO below the emission limit. PACE realizes that a 0-10 ppm span does not meet the span requirements set forth in Method 25A of being 1.5 to 2.5 times the applicable emission limit; however, it is essentially the lowest range that the analyzer is capable of being calibrated to and as previously stated allows for a detection limit sufficient to quantify EtO below the emission limit.

4.0 SAMPLING LOCATION

The oxidizer outlet sampling ports are located in a horizontal section of ductwork with an inside diameter of 29.5 inches, with two ports at 90° from each other on the same plane (located on the side and top of the duct). The sampling location is located 35 feet (420 inches) (EPA distance "A" = 14.2 diameters) upstream from the bend in duct to the stack exit and 20 feet (240 inches) (EPA distance "B" = 8.1 diameters) downstream from a bend in the duct (see Figure 4.2).

The procedures specified by EPA Method 1, "*Sample and Velocity Traverses for Stationary Sources*" will be followed to determine the number and location of traverse points used for the velocity traverses. According to the A & B distances, twelve total traverse points are required. All measurements will be field-verified and an accurate stack diagram with the sample location, stack dimensions, and the A & B distances will be included in the final report.

The appropriateness of the sample location will be evaluated by performing cyclonic flow and stratification checks prior to compliance testing. A twelve-point cyclonic flow check will be performed using Method 1 traverse points and six points in two ports. The sampling location is considered acceptable if the average cyclonic flow angle is less than 20°.

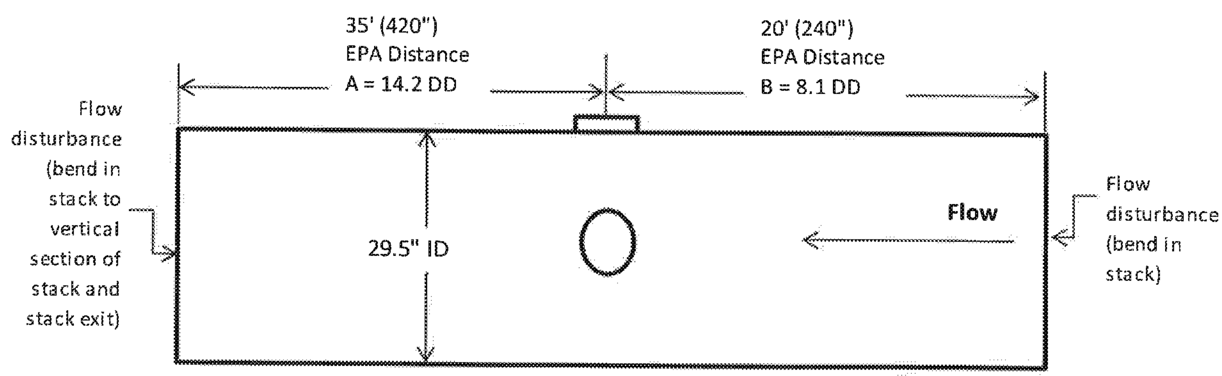
A three-point stratification check will also be performed using Method 7E traverse points and one port. If stratification is less than 5%, gaseous pollutant testing will be conducted at a single point in the stack. If stratification is between 5 and 10%, testing will occur at three CEM traverse points. Greater than 10% will result in a twelve-point traverse in one port during each test run.

Table 4.1 on the following page provides probe positions from the inner stack wall for both velocity/cyclonic flow and stratification traverses.

Table 4.1 Traverse Point Distances- Outlet

Traverse Point No.	Distance from Stack Wall (inches)		
	Stratification Check		Cyclonic & Volumetric Flow 12 Points (6 Points per Port)
	3 Points (1 Port Only)	12 Points (1 Port Only)	
1	4.9	0.6	1.3
2	14.8	2.0	4.3
3	24.6	3.5	8.7
4	----	5.2	20.8
5	----	7.4	25.2
6	----	10.5	28.2
7	----	19.0	----
8	----	22.1	----
9	----	24.3	----
10	----	26.0	----
11	----	27.5	----
12	----	28.9	----

Figure 4.2 Outlet Sampling Location Diagram



5.0 SAMPLING PROCEDURES

Emissions will be sampled and calculated using the additional information below:

- Location of the sampling points within the stack (using U.S. EPA Method 1)
- Measurement of volumetric flow rate using a Pitot tube (using U.S. EPA Method 2)
- Stack gas dry molecular weight (using U.S. EPA Method 3A)
- Moisture content in the exhaust gas (using U.S. EPA Method 4)

5.1 PACE Environmental's Continuous Emission Monitoring System

PACE operates a gaseous emissions measurement system that meets the performance criteria outlined in 40 CFR 60 Appendix A. The gas sample will be continuously extracted from the effluent gas stream and will be conveyed to the instrumental analyzer for determination of pollutant/diluent concentrations.

A data acquisition system (DAS) will be used to collect and log the data obtained from the analyzers. The DAS will record readings once every 5 seconds and reports the results in one-minute averages. Only one primary DAS will be used to capture calibration and test data.

A heated sample line will be used to transport the gas to the moisture removal system. The CEMS splits the sample, so a portion bypasses the conditioner and is sent directly to the hydrocarbon analyzer for simultaneous measurement of unconditioned, wet hydrocarbons, while the remainder of the sample is pulled through the conditioner. Sampling system temperatures will be recorded every fifteen minutes during each test run.

The moisture removal system will be a refrigerator-type condenser or equivalent to remove condensate from the sample gas while maintaining minimal contact between the condensate and the sample gas. A sample transport line will be used to transport the sample from the moisture removal system (except for M25A) to the sample pump, sample flow rate control and sample gas manifold.

The calibration valve assembly with a three-way valve assembly or equivalent will be used for introducing calibration gases either directly to the analyzer in direct calibration mode or into the measurement system at the probe in system calibration mode. A heated out-of-stack particulate filter will be used and included in the system bias test. A leak free pump will be used to pull the sample gas through the stream at a flow rate sufficient to minimize the response time of the measurement system. The pump will be constructed of any material that is non-reactive to the gas being sampled.

For calibration of the instrument, the span of the monitoring system is equivalent to the high-level calibration gas value (or 1.5 to 2.5 times the applicable emission limit for 25A) and will be selected such that is practicable, the in-stack emissions will be between 20-100% of the selected calibration span. If at any time during the run the measured gas concentration exceeds the readable range on the analyzer, the run may be considered invalid. If the average of any run exceeds the calibration span value, the run is invalid. When actual concentrations differ significantly from the standard, the span may need to be modified accordingly, such that the method criteria for span selection are met.

The **analyzer calibration error check** is performed on all analyzers (except the M25A FID) to establish the linearity and accuracy of the reference method analyzer. A total of three standards will be used to perform the direct calibration: a zero, a mid-range standard (40-60% of range), and a high-range standard (100% of range). The gases will be certified within an uncertainty of 2.0 percent in accordance with "EPA Traceability Protocol Assay and Certification of Gaseous Calibration Standards". If zero gas is used for the low-level gas, it shall meet the definition of "zero air material" in 40 CFR 72.2, as opposed to being an EPA Protocol gas.

During this check, no adjustments to the system will be made except those necessary to achieve the correct calibration gas flow rate to the analyzer. The analyzer responses to each calibration gas will be recorded. The analyzer calibration check will be considered invalid if the gas concentration displayed by the analyzer exceeds $\pm 2\%$ of the span for any of the calibration gases. For O_2 and CO_2 analyzers only, an alternate calibration allowable of 1.0% difference may be used.

Once the analyzer calibration error check has been successfully completed, the **sampling system bias check** is performed for all analyzers (including U.S. EPA Method 25A FIDs). This check will be performed by introducing first an upscale gas (mid-range or high level, whichever more closely approximates the stack concentration) at the calibration valve assembly installed at the outlet of the sampling probe, and then the zero gas. During this check, no adjustments to the system will be made except those necessary to achieve the correct calibration gas flow at the analyzer. This check will be considered invalid if the difference between the calibration bias check and the calibration error check for the same calibration gas exceeds $\pm 5\%$ of the span.

For Method 25A, the low-, mid-, and high-range standards (25-35%, 45-55%, and 80-90% of range) will be introduced at the junction of the heated hose and probe, after using and adjusting to the zero gas. The response to the three upscale standards must be within 5% of the certified value of each standard.

During the initial sampling system bias check, the measurement system response time is determined, as in Sections 8.2.5 & 8.2.6 of Method 7E (and Section 8.5 of M25A for the FID).

Documentation that the interference checks have been conducted in accordance with Section 8.2.7 of Method 7E will be made available on site and in the final report.

Stratification Determination will occur prior to sampling or as the first part of the first test run. The test will be performed in accordance with Section 8.1.2 of Method 7E. More than one instrumental test is being performed which requires the stratification to be performed only one time.

The stratification check will be conducted at three traverse points spaced on a line passing through the centroidal area at 16.7, 50.0 and 83.3 percent of the measurement line (See Tables 4.1 & 4.3 for stratification check point distances). Each point will be sampled for a minimum of twice the response time. The minimum number of traverse points required for sampling will be determined as outlined in Table 5.1 below.

Table 5.1 Stratification Test Criteria

Difference from mean	Stratification Class	Number of required sample points
±5%, or ±0.3% O_2 or CO_2 (as applicable)	Un-stratified	A single point that most closely matches the mean
Between ±5% and ±10%, or ±0.5% O_2 or CO_2	Minimally stratified	Three (3) sample points spaced at 16.7, 50.0 and 83.3 percent of the measurement line.
Greater than ±10%, and greater than ±0.5% O_2 or CO_2	Stratified	Twelve (12) sample points located consistent with EPA Method 1 criteria

Prior to starting the emission measurement test procedures, the sampling probe will be placed at the first sample point and sampling will begin at the same rate as the bias check. A constant rate of ±10% will be maintained during the entire sample run. Sampling will commence only after twice the response time has elapsed. Sampling will be conducted for an equal length of time at each traverse point.

Immediately following the completion of the test period and hourly during the test period, the zero calibration gas and an upscale calibration gas (mid-level or high-level as appropriate) will be re-introduced one at a time to the measurement system at the calibration valve assembly. No adjustments to the measurement system will be made until both low and upscale bias and drift checks are made. The analyzer response will be recorded.

If the post-run zero- and upscale bias (or 2-point system calibration error) checks are passed, but the zero or upscale drift exceeds ±3% of the span value, the run data are valid, but a 3- point calibration error test and a system bias (or 2-point system calibration error) check must be performed and passed before any more test runs are done.

For each test run, the pollutant/diluent run averages (except for M25A) will be adjusted for bias using Method 7E Equation 7E-5a if a non-zero gas is used for the low level calibration gas, or Equation 7E-5b if a zero gas is used as the low-level calibration gas.

The **measurement system performance specifications** are as follows:
Calibration Error: less than or equal to ±2% of the span for each calibration gas will be acceptable.
Sampling System Bias: less than or equal to ±5% of the span value (or bottle value for M25A) for the zero- level or upscale gas relative to the response of the analyzer during the calibration error check will be acceptable.
Drift: less than or equal to ±3% of the span value for the zero-level or upscale gas will be acceptable.

5.2 Oxygen and Carbon Dioxide

Summary: Sampling of O_2 and CO_2 on the outlet will be conducted in accordance with U.S. EPA Method 3A, "Determination of Oxygen and Carbon Dioxide Concentrations in Emissions from Stationary Sources (Instrumental Analyzer Procedure)". A continuous gas sample is extracted from a sampling point and analyzed for O_2 and CO_2 using a CAI ZRE analyzer or equivalent.

The analyzer measures concentrations of O_2 using a built-in fuel cell. CO_2 concentrations in the sample gas are measured using the NDIR absorption method. The NDIR operates on the principle that different atomic molecules have an absorption spectrum in the wave band of infrared rays. The intensity of absorption is determined using the Lambert-Beer Law. Following Beer's Law, the absorbance is proportional to the concentration of the associated sample gas.

Calibration Gases: The calibration gases used will be U.S. EPA Protocol I standards of O_2 and CO_2 for instrument span, and pre-purified N_2 for zero. Protocol I standards will be zero, 40-60%, and 100% of range. **The approximate calibration gas standards to be used for O_2 are 0%, 11.5% and 23%. The approximate calibration gas standards to be used for CO_2 are 0%, 5% and 10%.**

The calibration gases for the analyzer will be CO_2 in N_2, CO_2 in air or a calibration gas mixture as indicated in Section 7.1 of the method.

5.3 Ethylene Oxide

Summary: Ethylene oxide will be measured in accordance with U.S. EPA Method 25A. A continuous gas sample is extracted from the outlet stack and analyzed for EtO using a flame ionization detector (FID). The instrumental analyzer to be used during this test program is a VIG 200 or equivalent.

Calibration Gases: The calibration gases for the FID analyzer will be certified standards of EtO in nitrogen for instrument span, and pre-purified N_2 for zero. Calibration gas standards will be zero, 25-35%, 45-55% and 80-90% of the span value, in accordance with Method 25A. **The approximate calibration gas standards to be used are 0 ppm, 3 ppm, 5 ppm and 8.5 ppm.**

Sample System Operation: A representative exhaust gas sample is extracted from the emission source through a stainless-steel probe, heated Teflon sample line and heated pre-filter prior to being introduced to the instrument for immediate analysis. The system allows for transporting filtered stack gases to the individual instruments while maintaining the temperature well above the dew point of the gases. All instrument outputs are recorded by a paperless computer-based data acquisition system (DAS).

The FID uses a well-controlled flame to combust the hydrocarbons within the gas stream. Burner oven temperature is fixed at 190 degrees Celsius. Hydrocarbons are ionized by the flame, and the detector (typically a thin, platinum wire) measures this ionization energy of the carbon-hydrogen bonds that are broken. The detector's response is directly related to the number of carbon atoms contained in each organic molecule of the sample. Output from the detector is electronically converted into a concentration based on the compound (i.e. ethylene oxide) used to calibrate the FID.

5.4 Moisture

Summary: Moisture content will be measured on the outlet stack in accordance with U.S. EPA Method 4, "Determination of Moisture Content in Stack Gases". A gas sample is extracted at a constant rate; moisture is removed from the sample stream and determined gravimetrically.

Equipment: A condenser consisting of four impingers connected in a series with ground glass, leak-free fittings or any similar non-contaminating fittings will be used. The first, third and fourth impingers will be Greenburg-Smith design, modified by replacing the tip with a 1.3 cm. (1/2 in.) ID glass tube extending to about 1.3 cm from the bottom of the flask. The second impinger will be a Greenburg-Smith design with a standard tip. The first two impingers will contain known volumes of water, the third will be empty and the fourth will contain a known weight of 6 to 16 mesh indicating type silica gel, or equivalent desiccant. An ice bath container and crushed ice will be used as the cooling system to aid in condensing moisture.

The metering system used will be capable of measuring the volume within ±2%. It will include a vacuum gauge, leak-free pump, thermometers capable of measuring temperature within 3 degrees Celsius (°C) (5.4 degrees Fahrenheit (°F)) and a dry gas meter capable of measuring volume within ±2%. Atmospheric pressure will be looked up from historical logs kept by local national weather stations. A balance will be used to measure the condensed water and silica gel in the impingers to within 0.5 gram (g) or less.

A minimum total gas volume of 0.60 scm (21 scf) will be collected, at a rate no greater than 0.021 m^3/min (0.75 cfm). The moisture determination will be conducted simultaneous with, and for the same amount of time as, the pollutant emission run.

A Method 4 moisture train sampling diagram is included in Appendix II.

Sampling: After the impingers are iced down, a leak check will be performed with an acceptable rate of 4 percent of the average sampling rate or 0.02 cfm, whichever is less. During the run the sampling rate will be maintained within 10 percent of the constant rate. The dry gas meter will be recorded at the beginning and end of each sampling time increment and whenever the sampling is halted. More ice will be added, if necessary, to maintain a temperature of less than 20°C (68°F) at the silica gel outlet. When the run is complete, a post leak check is performed, and then the condensed moisture is measured to the nearest 0.5 g.

5.5 Volumetric Flow Rate

Summary: The oxidizer outlet volumetric flow rate will be measured in accordance with U.S. EPA Method 1, "Sample and Velocity Traverses for Stationary Sources" and U.S. EPA Method 2, "Determination of Stack Gas Velocity and Volumetric Flow Rate (Type S Pitot Tube)". A calibrated Type S Pitot tube is used to measure differential pressure readings across a stack. Temperature, pressure, and molecular weight of the gas are also measured to determine the average stack gas velocity.

Traverse points and sampling diagrams are included in Section 4.0.

Equipment: The following equipment will be used for flow measurements:

- S Type Pitot tube meeting the requirements of Method 2 Sections 6.1.1 and 6.1.2
- Inclined manometer- both a standard 10 inches water column ("WC) inclined vertical manometer and a mini-manometer of higher sensitivity with an approximate scale of 0.25"WC
- Type K thermocouple for stack temperature measurement

Sampling: The pre-test leak check of the Pitot tube and inclined manometer will be conducted as per Section 8.1 of the method. The manometer will be leveled and zeroed prior to use as well as periodically checked. The velocity head and temperatures will be measured at each traverse point. Ports will be stuffed to ensure sample integrity.

NESHAP Subpart O recommends measuring flow rate at one-minute intervals. We propose to perform a complete set of flow traverses during normal process operations. The average differential pressure (Δp) reading will be calculated, and the pitot tube will be secured in the stack at the traverse point with the reading closest to the average Δp value. The Δp and stack temperature will be recorded at one-minute intervals during each run. The pitot tube will be monitored frequently to ensure proper alignment within the stack.

The static pressure in the stack will be measured during the test as well as the atmospheric pressure. The stack gas dry molecular weight and moisture content will be determined in accordance with EPA Methods 3A and 4, respectively.

All calculations will be performed in accordance with Section 12 of the method.

Verification of cyclonic flow will be performed per section 11.4 of Method 1 prior to the start of sampling. Documentation will be supplied to the on-site observer and included in the final report. No deviations are proposed.

6.0 QUALITY ASSURANCE/QUALITY CONTROL

This test protocol was developed in accordance with the principles and recommendations outlined in the U.S. EPA Quality Assurance Handbook for Air Pollution Measurement Systems.

6.1 Audit Samples

No audit samples are required for this test program.

6.2 Chain of Custody

The procedures to be followed during this test program provide real-time data. Therefore, no chain-of-custody documentation will be necessary.

6.3 Calibration Data

All pre-test calibration data for sampling and equipment will be made available onsite, at the time of testing to any regulatory representatives. Copies of all calibration data will be included in the final report.

6.4 Calibration Procedures

Detailed standard operating procedures (SOPs) for applicable equipment and instrumentation are documented in the Quality Assurance/ Quality Control Manual and are summarized below.

Pitot Tubes: All S-Type Pitot tubes are initially provided a C_p of 0.84 by the manufacturer, in accordance with the specifications listed in U.S. EPA Method 2.1.

Before each use, a visual inspection of the Pitot tube is made to verify that the face openings are in alignment within the specifications shown in Figure 2-2 and 2-3 of U.S. EPA Method 2.

Dry Gas Meters: Critical orifices are used as the calibration standard, in accordance with U.S. EPA Method 5, Section 16.2. The dry gas meter is calibrated before and after each use. If the dry gas meter coefficient obtained before and after the test series differ by more than five percent, the calculations for the test series will be performed using the coefficient that gives the lower value of sample volume.

Thermocouples: Thermocouples are calibrated using an Omega Temperature Calibrator. The thermocouples are consecutively checked with a range of varying temperatures. If the absolute temperature reading between the thermocouple and the Omega agree within ±1.5% at all of the calibration points, the actual thermocouple reading is considered acceptable.

Calibration Gas Certifications: Calibration gas certificates are provided by the supplier and copies will be included in the final test report.

7.0 REPORTING/RESULTS

Emissions of EtO will be reported as ppmvd during both sterilization and aeration room test scenarios. EtO emissions reduction during sterilization will be calculated and reported as a percent, based on mass (as grams or pounds) as EtO inlet/outlet results.

The first page of the report will contain the Test Results Summary (TRS). The TRS will contain a table listing the test date(s); the source and source ID numbers; the average result(s) of each pollutant measured in units of the permit limit(s); permit limit(s) for each pollutant measured; permit number(s) where limit was obtained; and whether results demonstrate compliance or non-compliance with permit limit(s). All results in the TRS will be reported to three significant figures; emission calculations/supporting documentation will be reported to at least five significant figures.

The PADEP laboratory registration ID for any company engaged in the testing or analysis of environmental samples will be included in the final report.

A summary of the emissions results, including a comparison to the permitted emission limits, will be a fundamental part of the final test report. A copy of the complete report will be submitted to the PADEP Central and Northeast regional office and the U.S. EPA Region 3 office within 60 days of the test date.

8.0 CERTIFICATION

We, the undersigned, certify that *to the best of our knowledge*, the state and federal regulations, operating permits, or plan approvals applicable to each source or control device to be tested have been reviewed and that all testing requirements therein have been incorporated in this test plan.

Submitted by:

Erica L. Bolek
QA/QC Manager
PACE Environmental

Representative of the source owner/operator:

Signature

ERIC GEDER

Name

EHS & S MANAGER

Title

APPENDIX I

Applicable Pages of the Facility Permit

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF ENVIRONMENTAL PROTECTION
AIR QUALITY PROGRAM

PLAN APPROVAL

Issue Date: January 30, 2020 Effective Date: January 30, 2020

Expiration Date: January 30, 2021

In accordance with the provisions of the Air Pollution Control Act, the Act of January 8, 1960, P.L. 2119, as amended, and 25 Pa. Code Chapter 127, the Owner, [and Operator if noted] (hereinafter referred to as permittee) identified below is authorized by the Department of Environmental Protection (Department) to construct, install, modify or reactivate the air emission source(s) more fully described in the site inventory list. This Facility is subject to all terms and conditions specified in this plan approval. Nothing in this plan approval relieves the permittee from its obligations to comply with all applicable Federal, State and Local laws and regulations.

The regulatory or statutory authority for each plan approval condition is set forth in brackets. All terms and conditions in this permit are federally enforceable unless otherwise designated as "State-Only" requirements.

Plan Approval No. 39-00055B

Federal Tax Id - Plant Code: 23-2116774-1

Owner Information

Name: B BRAUN MED INC
Mailing Address: 901 MARCON BLVD
ALLENTOWN, PA 18109-9512

Plant Information

Plant: B BRAUN MED INC/ALLENTOWN
Location: 39 Lehigh County 39910 Hanover Township
SIC Code: 3841 Manufacturing - Surgical And Medical Instruments

Responsible Official

Name: REX BOLAND
Title: V.P. & G.M. ALLENTOWN OP.
Phone: (610) 596 - 2870

Plan Approval Contact Person

Name: ERIC GEDER
Title: EH&S MGR
Phone: (484) 240 - 8817

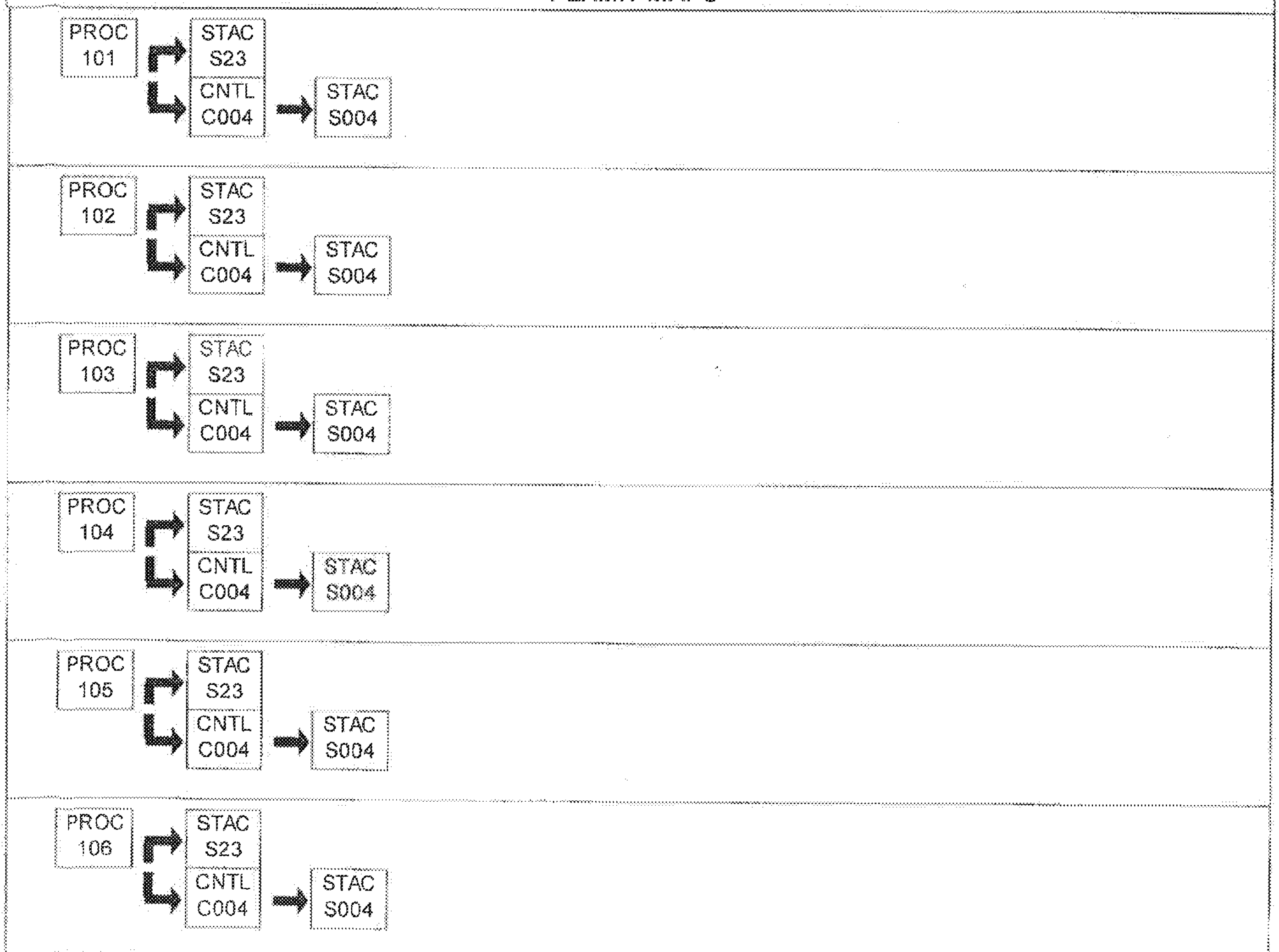
[Signature]

MARK J. WEJKSZNER, NORTHEAST REGION AIR PROGRAM MANAGER

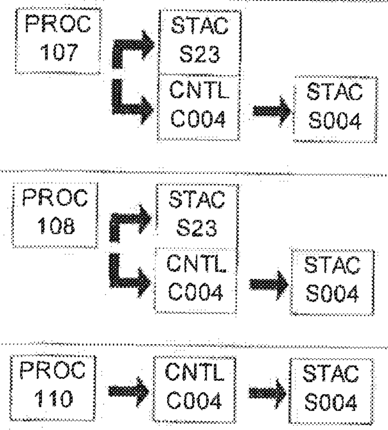
SECTION A. Plan Approval Inventory List

Source ID	Source Name	Capacity/Throughput	Fuel/Material
101	STERILIZER - 1000 CU FT		
102	STERILIZER - 1000 CU FT		
103	STERILIZER - 1000 CU FT		
104	STERILIZER - 1000 CU FT		
105	STERILIZER - 1200 CU FT		
106	STERILIZER - 1250 CU FT		
107	STERILIZER - 3700 CU FT		
108	STERILIZER - 130 CU FT		
110	AERATION ROOM		
C004	CATALYTIC OXIDIZER WITH PEAK SHAVER		
S004	CATALYTIC OXIDIZER STACK		
S23	COMMON REAR STERILIZER EXHAUST STACK		

PERMIT MAPS



PERMIT MAPS


PROC 107
STAC S23
CNTL C004
STAC S004
PROC 108
STAC S23
CNTL C004
STAC S004
PROC 110
CNTL C004
STAC S004

SECTION E. Source Group Plan Approval Restrictions.

Group Name: GROUP 1
Group Description: ETO STERLIZERS
Sources included in this group

ID	Name
101	STERILIZER - 1000 CU FT
102	STERILIZER - 1000 CU FT
103	STERILIZER - 1000 CU FT
104	STERILIZER - 1000 CU FT
105	STERILIZER - 1200 CU FT
106	STERILIZER - 1250 CU FT
107	STERILIZER - 3700 CU FT
108	STERILIZER - 130 CU FT
110	AERATION ROOM

I. RESTRICTIONS.

Emission Restriction(s).

 # 001 [40 CFR Part 63 NESHAPS for Source Categories §40 CFR 63.362]
Subpart O -- Ethylene Oxide Emissions Standards for Sterilization Facilities
Standards.

(a) Each owner or operator of a source subject to the provisions of this subpart shall comply with these requirements on and after the compliance date specified in Sec. 63.360(g). The standards of this section are summarized in Table 1 of this section.

Table 1 of Section 63.362.-- Standards for Ethylene Oxide Commercial Sterilizers and Fumigators

Existing and New sources	Source type	Sterilization chamber vent	Aeration room vent	Chamber exhaust vent
Source size	<907 kg (<1 ton)	No controls required; minimal recordkeeping requirements apply (see Sec. 63.367(c)).		
	>=907 kg and <9,070 kg (>=1 ton and <10 tons).	99% emission reduction (see Sec. 63.362(c)).	No control	No control
	>=9,070 kg (>=10 tons)	99% emission reduction (see Sec. 63.362(c)).	1 ppm maximum outlet concentration or 99% emission reduction (see Sec. 63.362(d)).	No control

1 Affected sources may show compliance by manifolding emissions to a control device used to comply with Sec. 63.362 (c) or (d) by reducing emissions by at least 99 percent.

(b) Applicability of emission limits. The emission limitations of paragraphs (c), (d), and (e) of this section apply during sterilization operation. The emission limitations do not apply during periods of malfunction.

(c) Sterilization chamber vent at sources using 1 ton. Each owner or operator of a sterilization source using 1 ton shall reduce ethylene oxide emissions to the atmosphere by at least 99 percent from each sterilization chamber vent.

(d) Aeration room vent at sources using 10 tons. Each owner or operator of a sterilization source using 10 tons shall reduce ethylene oxide emissions to the atmosphere from each aeration room vent to a maximum concentration of 1 ppmv or by at least 99 percent, whichever is less stringent, from each aeration room vent.

Throughput Restriction(s).

 # 002 [25 Pa. Code §127.12b]

Plan approval terms and conditions.

The permittee shall not exceed usage of 393,470 pounds of ethylene oxide at the sterilization chambers for any consecutive twelve (12) month period.

II. TESTING REQUIREMENTS.

 # 003 [25 Pa. Code §127.12b]

Plan approval terms and conditions.

(a) If the results of a stack test, performed as required by this approval, exceed the level specified in any condition of this approval, the Permitee shall take appropriate corrective actions. Within 30 days of the Permitee receiving the stack test results, a written description of the corrective actions shall be submitted to the Department. The Permitee shall take appropriate action to minimize emissions from the affected facility while the corrective actions are being implemented. The Department shall notify the Permitee within 30 days, if the corrective actions taken are deficient. Within 30 days of receipt of the notice of deficiency, the Permitee shall submit a description of additional corrective actions to the Department. The Department reserves the authority to use enforcement activities to resolve noncompliant stack tests.

(b) If the results of the required stack test exceed any limit defined in this plan approval, the test was not performed in accordance with the stack test protocol or the source and/or air cleaning device was not operated in accordance with the plan approval, then another stack test shall be performed to determine compliance. Within 120 days of the Permitee receiving the original stack test results, a retest shall be performed. The Department may extend the retesting deadline if the Permitee demonstrates, to the Department's satisfaction, that retesting within 120 days is not practicable. Failure of the second test to demonstrate compliance with the limits in the plan approval, not performing the test in accordance with the stack test protocol or not operating the source and/or air cleaning device in accordance with the plan approval may be grounds for immediate revocation of the plan approval to operate the affected source.

 # 004 [25 Pa. Code §127.12b]

Plan approval terms and conditions.

1. Source tests shall be conducted to demonstrate: (a) either the destruction/removal efficiency (DRE) of at least 99% (by weight) or an outlet EtO concentration of less than or equal to 1 ppmv (whichever is less stringent) for EtO emissions The Department reserves the right to require the owner or operator to conduct further tests at any time after the initial compliance tests.

2. At least sixty (60) calendar days prior to commencing an emission testing program required by this permit, a test protocol shall be submitted to the Department's Division of Source Testing and Monitoring and the Regional Office for review and approval. The test protocol shall meet all applicable requirements specified in the most current version of the Department's Source Testing Manual.

3. At least fifteen (15) calendar days prior to commencing an emission testing program required by this permit, written notification of the date and time of testing shall be provided to the Department's appropriate Regional Office. Written notification shall also be sent to the Department's Bureau of Air Quality, Division of Source Testing and Monitoring. The notification shall not be made without prior receipt of a protocol acceptance letter from the Department. The Department is under no obligation to accept the results of any testing performed without adequate advance written notice to the Deartment of such testing. In addition, the emissions testing shall not commence prior to receipt of a protocol acceptance letter from the Department.

4. A complete test report shall be submitted to the Department no later than sixty (60) calendar days after completion of the on-site testing portion of an emission test program.

5. A complete test report shall include a summary of the emission results on the first page of the report indicating if each pollutant measured is within permitted limits and a statement of compliance or non-compliance with all applicable permit conditions. The summary results will include, at a minimum, the following information:

i. A statement that the owner or operator has reviewed the report from the emissions testing body and agrees with the findings;

ii. Permit number(s) and condition(s) which are the basis for the evaluation;

iii. Summary of results with respect to each applicable permit condition; and

iv. Statement of compliance or non-compliance with each applicable permit condition.

 # 005 [40 CFR Part 63 NESHAPS for Source Categories §40 CFR 63.365]
Subpart O -- Ethylene Oxide Emissions Standards for Sterilization Facilities
Test methods and procedures.

(a) Performance testing. The owner or operator of a source subject to the emissions standards in Sec. 63.362 shall comply with the performance testing requirements in Sec. 63.7 of subpart A of this part, according to the applicability in Table 1 of Sec. 63.360, and in this section.

(b) First evacuation of the sterilization chamber. These procedures shall be performed on an empty sterilization chamber, charged with a typical amount of ethylene oxide, for the duration of the first evacuation under normal operating conditions (i.e., sterilization pressure and temperature).

(1) First evacuation of the sterilization chamber. These procedures shall be performed on an empty sterilization chamber, charged with a typical amount of ethylene oxide, for the duration of the first evacuation under normal operating conditions (i.e., sterilization pressure and temperature).

(i) The amount of ethylene oxide loaded into the sterilizer (Wc) shall be determined by either:

(A) Weighing the ethylene oxide gas cylinder(s) used to charge the sterilizer before and after charging. Record these weights to the nearest 45 g (0.1 lb). Multiply the total mass of gas charged by the weight percent ethylene oxide present in the gas.

(B) Installing calibrated rotameters at the sterilizer inlet and measuring flow rate and duration of sterilizer charge. Use the following equation to convert flow rate to weight of ethylene oxide:

where:

Wc=weight of ethylene oxide charged, g (lb)
Fv=volumetric flow rate, liters per minute (L/min) corrected to 20 deg.C and 101.325 kilopascals (kPa) (scf per minute (scfm) corrected to 68 deg.F and 1 atmosphere of pressure (atm)); the flowrate must be constant during time (t)t=time, min
%EOv=volume fraction ethylene oxide
SV=standard volume, 24.05 liters per mole (L/mole)=22.414 L/mole ideal gas law constant corrected to 20 deg.C and 101.325 kPa (385.32 scf per mole (scf/mole)=359 scf/mole ideal gas law constant corrected to 68 deg.F and 1 atm).
MW=molecular weight of ethylene oxide, 44.05 grams per gram-mole (g/g-mole) (44.05 pounds per pound-mole (lb/lb-mole)), or

(C) Calculating the mass based on the conditions of the chamber immediately after it has been charged using the following equation:

where:

P=chamber pressure, kPa (psia)
V=chamber volume, liters (L) (ft3)
R=gas constant, 8.313 L(kPa/g-mole((10.73 psia(ft3/mole (R)
T=temperature, K ((R)

Note: If the ethylene oxide concentration is in weight percent, use the following equation to calculate mole fraction:

where;

WEO=weight percent of ethylene oxide
Wx=weight percent of compound in the balance of the mixture
MWx=molecular weight of compound in the balance gas mixture

(ii) The residual mass of ethylene oxide in the sterilizer shall be determined by recording the chamber temperature, pressure, and volume after the completion of the first evacuation and using the following equation:

where:

Wr=weight of ethylene oxide remaining in chamber (after the first evacuation), in g (lb)

(iii) Calculate the total mass of ethylene oxide at the inlet to the control device (Wi) by subtracting the residual mass (Wr) calculated in paragraph (b)(1)(ii) of this section from the charged weight (Wc) calculated in paragraph (b)(1)(i) of this section.

(iv) The mass of ethylene oxide emitted from the control device outlet (Wo) shall be calculated by continuously monitoring the flow rate and concentration using the following procedure.

(A) Measure the flow rate through the control device exhaust continuously during the first evacuation using the procedure found in 40 CFR part 60, appendix A, Test Methods 2, 2A, 2C, or 2D, as appropriate. (Method 2D (using orifice plates or Rootstype meters) is recommended for measuring flow rates from sterilizer control devices.) Record the flow rate at 1-minute intervals throughout the test cycle, taking the first reading within 15 seconds after time zero. Time zero is defined as the moment when the pressure in the sterilizer is released. Correct the flow to standard conditions (20 deg.C and 101.325 kPa (68 deg.F and 1 atm)) and determine the flow rate for the run as outlined in the test methods listed in paragraph (b) of this section.

(B) Test Method 18 or 25A, 40 CFR part 60, appendix A (hereafter referred to as Method 18 or 25A, respectively), shall be used to measure the concentration of ethylene oxide.

(1) Prepare a graph of volumetric flow rate versus time corresponding to the period of the run cycle. Integrate the area under the curve to determine the volume.

(2) Calculate the mass of ethylene oxide by using the following equation:

where:
Wo=Mass of ethylene oxide for each bag, g (lb)
C=concentration of ethylene oxide in ppmv
V=volume of gas exiting the control device corrected to standard conditions, L (ft3)
1/106=correction factor LEO/106 L TOTAL GAS (ft3EO/106ft3TOTAL GAS)

(3) Calculate the efficiency by the equation in paragraph (b)(1)(v) of this section.

(C) [Reserved]

(v) Determine control device efficiency (% Eff) using the following equation:

where:

% Eff = percent efficiency
Wi = mass flow rate into the control device
Wo = mass flow rate out of the control device

(vi) Repeat the procedures in paragraphs (b)(1) (i) through (v) of this section three times. The arithmetic average percent efficiency of the three runs shall determine the overall efficiency of the control device.

(2) [Reserved]

(c) Concentration determination. The following procedures shall be used to determine the ethylene oxide concentration.

(1) Parameter monitoring. For determining the ethylene oxide concentration required in Sec. 63.364(e), follow the procedures in PS 8 or PS 9 in 40 CFR part 60, appendix B. Sources complying with PS 8 are exempt from the relative accuracy procedures in sections 2.4 and 3 of PS-8.

(2) Initial compliance. For determining the ethylene oxide concentration required in Sec. 63.363(c)(2), the procedures outlined in Method 18 or Method 25 A (40 CFR part 60, appendix A) shall be used. A Method 18 or Method 25A test consists of three 1-hour runs. If using Method 25A to determine concentration, calibrate and report Method 25A instrument results using ethylene oxide as the calibration gas. The arithmetic average of the ethylene oxide concentration of the three test runs shall determine the overall outlet ethylene oxide concentration from the control device.

(d) Efficiency determination at the aeration room vent (not manifolded). The following procedures shall be used to determine the efficiency of a control device used to comply with Sec. 63.362(d), the aeration room vent standard.

(1) Determine the concentration of ethylene oxide at the inlet and outlet of the control device using the procedures in Method 18 or 25A in 40 CFR part 60, appendix A. A test is comprised of three 1-hour runs.

(2) Determine control device efficiency (% Eff) using the following equation:

Where:

% Eff = percent efficiency
W<INF>i</INF> = mass flow rate into the control device
W<INF>O</INF> = mass flow rate out of the control device

(3) Repeat the procedures in paragraphs (d)(1) and (2) of this section three times. The arithmetic average percent efficiency of the three runs shall determine the overall efficiency of the control device.

(e) Determination of baseline parameters for acid-water scrubbers. The procedures in this paragraph shall be used to determine the monitored parameters established in Sec. 63.363(b), (d), or (e) for acid-water scrubbers and to monitor the parameters as established in Sec. 63.364(b).

(1) Ethylene glycol concentration. For determining the ethylene glycol concentration, the facility owner or operator shall establish the maximum ethylene glycol concentration as the ethylene glycol concentration averaged over three test runs; the sampling and analysis procedures in ASTM D 3695-88, Standard Test Method for Volatile Alcohols in Water By Direct Aqueous-Injection Gas Chromatography, (incorporated by reference--see Sec. 63.14) shall be used to determine the ethylene glycol concentration.

(2) Scrubber liquor tank level. For determining the scrubber liquor tank level, the sterilization facility owner or operator shall establish the maximum liquor tank level based on a single measurement of the liquor tank level during one test run.

(f) [Reserved]

(g) An owner or operator of a sterilization facility seeking to demonstrate compliance with the standards found at Sec. 63.362(c), (d), or (e) with a control device other than an acid-water scrubber or catalytic or thermal oxidation unit shall provide to the Administrator the information requested under Sec. 63.363(f). The owner or operator shall submit: a description of the device; test results collected in accordance with Sec. 63.363(f) verifying the performance of the device for controlling ethylene oxide emissions to the atmosphere to the levels required by the applicable standards; the appropriate operating parameters that will be monitored; and the frequency of measuring and recording to establish continuous compliance with the standards. The monitoring plan submitted identifying the compliance monitoring is subject to the Administrator's approval. The owner or operator of the sterilization facility shall install, calibrate, operate, and maintain the monitor(s) approved by the Administrator based on the information submitted by the owner or operator. The owner or operator shall include in the information submitted to the Administrator proposed performance specifications and quality assurance procedures for their monitors. The Administrator may request further information and shall approve appropriate test methods and procedures.

(h) An owner or operator of a sterilization facility seeking to demonstrate compliance with the requirements of Sec. 63.363 or Sec. 63.364, with a monitoring device or procedure other than a gas chromatograph or a flame ionization analyzer, shall provide to the Administrator information describing the operation of the monitoring device or procedure and the parameter(s) that would demonstrate continuous compliance with each operating limit. The Administrator may request further information and will specify appropriate test methods and procedures.

III. **MONITORING REQUIREMENTS.**

 # 006 [25 Pa. Code §127.12b]
Plan approval terms and conditions.

a) Temperature sensing and recording devices shall be installed to show that the inlet temperature to the catalyst bed meets or exceeds the minimum inlet temperature for effective oxidation based on manufacturer specifications.

b) The company shall ensure that the control devices shall be equipped with the applicable monitoring equipment and the monitoring equipment shall be installed, calibrated, operated, and maintained according to the vendor's specifications at all times the control device is in use.

c) Prior to the performance test, the inlet temperature to the catalyst bed shall be continuously monitored and operated at or above the minimum inlet temperature to the combustion bed per manufacturer specifications. After completion of the initial performance test, the temperature to the catalyst bed shall be continuously monitored and operated at or above the minimum inlet temperature to the oxidation catalyst, achieved during the performance test during which compliance was demonstrated.

 # 007 [40 CFR Part 63 NESHAPS for Source Categories §40 CFR 63.363]
Subpart O -- Ethylene Oxide Emissions Standards for Sterilization Facilities
Compliance and performance provisions.

(a) (1) The owner or operator of a source subject to emissions standards in Sec. 63.362 shall conduct an initial performance test using the procedures listed in Sec. 63.7 according to the applicability in Table 1 of Sec. 63.360, the procedures listed in this section, and the test methods listed in Sec. 63.365.

(2) The owner or operator of all sources subject to these emissions standards shall complete the performance test within 180 days after the compliance date for the specific source as determined in Sec. 63.360(g).

(b) The procedures in paragraphs (b)(1) through (3) of this section shall be used to determine initial compliance with the emission limits under Sec. 63.362(c), the sterilization chamber vent standard and to establish operating limits for the control devices:

(1) The owner or operator shall determine the efficiency of control devices used to comply with Sec. 63.362(c) using the test methods and procedures in Sec. 63.365(b).

(2) For facilities with acid-water scrubbers, the owner or operator shall establish as an operating limit either:

(i) The maximum ethylene glycol concentration using the procedures described in Sec. 63.365(e)(1); or

(ii) The maximum liquor tank level using the procedures described in Sec. 63.365(e)(2).

(3) For facilities with catalytic oxidizers or thermal oxidizers, the operating limit consists of the recommended minimum oxidization temperature provided by the oxidation unit manufacturer for an operating limit.

(4) Facilities with catalytic oxidizer shall comply with one of the following work practices:

(i) Once per year after the initial compliance test, conduct a performance test during routine operations, i.e., with product in the chamber using the procedures described in Sec. 63.365(b) or (d) as appropriate. If the percent efficiency is less than 99 percent, restore the catalyst as soon as practicable but no later than 180 days after conducting the performance test; or

(ii) Once per year after the initial compliance test, analyze ethylene oxide concentration data from Sec. 63.364(e) or a continuous emission monitoring system (CEMS) and restore the catalyst as soon as practicable but no later than 180 days after data analysis; or

(iii) Every 5 years, beginning 5 years after the initial compliance test (or by December 6, 2002, whichever is later), replace the catalyst bed with new catalyst material.

(c) The procedures in paragraphs (c)(1) through (3) of this section shall be used to determine initial compliance with the emission limits under Sec. 63.362(d), the aeration room vent standard:

(1) The owner or operator shall comply with either paragraph (b)(2) or (3) of this section.

(2) Determine the concentration of ethylene oxide emitted from the aeration room into the atmosphere (after any control device used to comply with Sec. 63.362(d)) using the methods in Sec. 63.365(c)(1); or

(3) Determine the efficiency of the control device used to comply with Sec. 63.362(d) using the test methods and procedures in Sec. 63.365(d)(2).

(d) [Reserved]

(e) For facilities complying with the emissions limits under Sec. 63.362 with a control technology other than acid-water scrubbers or catalytic or thermal oxidizers, the owner or operator of the facility shall provide to the Administrator or delegated authority information describing the design and operation of the air pollution control system, including recommendations for the operating parameters to be monitored to demonstrate continuous compliance. Based on this information, the Administrator will determine the operating parameter(s) to be measured during the performance test. During the performance test required in paragraph (a) of this section, using the methods approved in Sec. 63.365(g), the owner or operator shall determine the site-specific operating limit(s)for the operating parameters approved by the Administrator.

(f) A facility must demonstrate continuous compliance with each operating limit and work practice standard required under this section, except during periods of startup, shutdown, and malfunction, according to the methods specified in Sec. 63.364.

 # 008 [40 CFR Part 63 NESHAPS for Source Categories §40 CFR 63.364]
Subpart O -- Ethylene Oxide Emissions Standards for Sterilization Facilities
Monitoring requirements.

(a)(1) The owner or operator of a source subject to emissions standards in Sec. 63.362 shall comply with the monitoring requirements in Sec. 63.8 of subpart A of this part, according to the applicability in Table 1 of Sec. 63.360, and in this section.

(2) Each owner or operator of an ethylene oxide sterilization facility subject to these emissions standards shall monitor the parameters specified in this section. All monitoring equipment shall be installed such that representative measurements of emissions or process parameters from the source are obtained. For monitoring equipment purchased from a vendor, verification of the operational status of the monitoring equipment shall include completion of the manufacturer's written specifications or recommendations for installation, operation, and calibration of the system.

(b) For sterilization facilities complying with Sec. 63.363 (b) or (d) through the use of an acid-water scrubber, the owner or operator shall either:

(1) Sample the scrubber liquor and analyze and record once per week the ethylene glycol concentration of the scrubber liquor using the test methods and procedures in Sec. 63.365(e)(1). Monitoring is required during a week only if the scrubber unit has been operated; or

(2) Measure and record once per week the level of the scrubber liquor in the recirculation tank. The owner or operator shall install, maintain, and use a liquid level indicator to measure the scrubber liquor tank level (i.e., a marker on the tank wall, a dipstick, a magnetic indicator, etc.). Monitoring is required during a week only if the scrubber unit has been operated.

(c) For sterilization facilities complying with Sec. 63.363(b) or (c) through the use of catalytic oxidation or thermal oxidation, the owner or operator shall either comply with Sec. 63.364(e) or continuously monitor and record the oxidation temperature at the outlet to the catalyst bed or at the exhaust point from the thermal combustion chamber using the temperature monitor described in paragraph (c)(4) of this section. Monitoring is required only when the oxidation unit is operated. From 15-minute or shorter period temperature values, a data acquisition system for the temperature monitor shall compute and record a daily average oxidation temperature. Strip chart data shall be converted to record a daily average oxidation temperature each day any instantaneous temperature recording falls below the minimum temperature.

(1) [Reserved]

(2) [Reserved]

(3) [Reserved]

(4) The owner or operator shall install, calibrate, operate, and maintain a temperature monitor accurate to within <plus-minus>5.6 deg.C (<plus-minus>10 deg.F) to measure the oxidation temperature. The owner or operator shall verify the accuracy of the temperature monitor twice each calendar year with a reference temperature monitor (traceable to National Institute of Standards and Technology (NIST) standards or an independent temperature measurement device dedicated for this purpose). During accuracy checking, the probe of the reference device shall be at the same location as that of the temperature monitor being tested. As an alterative, the accuracy temperature monitor may be verified in a calibrated oven (traceable to NIST standards).

(d) For sterilization facilities complying with Sec. 63.363(b) or (c) through the use of a control device other than acid-water scrubbers or catalytic or thermal oxidizers, the owner or operator shall monitor the parameters as approved by the Administrator using the methods and procedures in Sec. 63.365(g).

(e) Measure and record once per hour the ethylene oxide concentration at the outlet to the atmosphere after any control device according to the procedures specified in Sec. 63.365(c)(1). The owner or operator shall compute and record a 24-hour average daily. The owner or operator will install, calibrate, operate, and maintain a monitor consistent with the requirements of performance specification (PS) 8 or 9 in 40 CFR part 60, appendix B, to measure ethylene oxide. The daily calibration requirements of section 7.2 of PS 9 or section 2.3 of PS 8 are required only on days when ethylene oxide emissions are vented to the control device.

IV. RECORDKEEPING REQUIREMENTS.

 # 009 [25 Pa. Code §127.12b]
Plan approval terms and conditions.

Pursuant to 25 Pa. Code § 135.5 (relating to recordkeeping), the owner or operator shall maintain and make available, upon request by the Department, such records as may be necessary to emonstrate compliance with 25 Pa. Code § 135.3 (relating to reporting). These records may include records of production, fuel usage, maintenance of production or pollution control equipment or other information determined by the Department to be necessary for identification and quantification of potential and actual air contaminant emissions. The records shall be retained for a minimum of five (5) years and shall be made available to the Department upon request.

 # 010 [25 Pa. Code §127.12b]
Plan approval terms and conditions.

The permittee shall maintain records which demonstrate compliance with the limit set in condition above and may be used by the Department for enforcement purposes. The records shall be updated on a monthly basis, shall be kept on site, and shall be provided to the Department personnel upon request.

 # 011 [25 Pa. Code §127.12b]
Plan approval terms and conditions.

Catalyst inlet temperature shall be recorded continuously whenever the unit is in operation. The temperature at the inlet to the catalyst bed shall be monitored and maintained to show that the unit is operating at or above the minimum inlet temperature to the oxidation catalyst achieved during the performance test in which compliance with the EtO destruction efficiency requirement is demonstrated. The recording charts shall be made available to the Department personnel upon request. These records shall be maintained for a period of time not less than five years.

SECTION E. Source Group Plan Approval Restrictions.

 # 012 [40 CFR Part 63 NESHAPS for Source Categories §40 CFR 63.367]
Subpart O -- Ethylene Oxide Emissions Standards for Sterilization Facilities
Recordkeeping requirements.

(a) The owner or operator of a source subject to Sec. 63.362 shall comply with the recordkeeping requirements in Sec. 63.10(b) and (c), according to the applicability in Table 1 of Sec. 63.360, and in this section. All records required to be maintained by this subpart or a subpart referenced by this subpart shall be maintained in such a manner that they can be readily accessed and are suitable for inspection. The most recent 2 years of records shall be retained onsite or shall be accessible to an inspector while onsite. The records of the preceding 3 years, where required, may be retained offsite. Records may be maintained in hard copy or computer-readable form including, but not limited to, on paper, microfilm, computer, computer disk, magnetic tape, or microfiche.

(b) The owners or operators of a source using 1 to 10 tons not subject to Sec. 63.362 shall maintain records of ethylene oxide use on a 12-month rolling average basis (until the source changes its operations to become a source subject to Sec. 63.362).

(c) The owners or operators of a source using less than 1 ton shall maintain records of ethylene oxide use on a 12-month rolling average basis (until the source changes its operations to become a source subject to Sec. 63.362).

(d) The owners or operators complying with Sec. 63.363(b) (4) shall maintain records of the compliance test, data analysis, and if catalyst is replaced, proof of replacement.

V. REPORTING REQUIREMENTS.

 # 013 [40 CFR Part 63 NESHAPS for Source Categories §40 CFR 63.366]
Subpart O -- Ethylene Oxide Emissions Standards for Sterilization Facilities
Reporting requirements.

(a) The owner or operator of a source subject to the emissions standards in Sec. 63.362 shall fulfill all reporting requirements in Secs. 63.10(a), (d), (e), and (f) of subpart A, according to the applicability in Table 1 of Sec. 63.360. These reports will be made to the Administrator at the appropriate address identified in Sec. 63.13 of subpart A of this part.

(1) Reports required by subpart A and this section may be sent by U.S. mail, fax, or by another courier.

(i) Submittals sent by U.S. mail shall be postmarked on or before the specified date.

(ii) Submittals sent by other methods shall be received by the Administrator on or before the specified date.

(2) If acceptable to both the Administrator and the owner or operator of a source, reports may be submitted on electronic media.

(3) Content and submittal dates for deviations and monitoring system performance reports. All deviations and monitoring system performance reports and all summary reports, if required per Sec. 63.10(e)(3)(vii) and (viii), shall be delivered or postmarked within 30 days following the end of each calendar half or quarter as appropriate (see Sec. 63.10(e)(3)(i) through (iv) for applicability). Written reports of deviations from an operating limit shall include all information required in Sec. 63.10(c)(5) through (13), as applicable in Table 1 of Sec. 63.360, and information from any calibration tests in which the monitoring equipment is not in compliance with PS 9 or the method used for temperature calibration. The written report shall also include the name, title, and signature of the responsible official who is certifying the accuracy of the report. When no deviations have occurred or monitoring equipment has not been inoperative, repaired, or adjusted, such information shall be stated in the report.

(b) Construction and reconstruction. The owner or operator of each source using 10 tons shall fulfill all requirements for construction or reconstruction of a source in Sec. 63.5 of subpart A of this part, according to the applicability in Table 1 of Sec. 63.360, and in this paragraph.

(1) Applicability.

(i) This paragraph and Sec. 63.5 of subpart A of this part implement the preconstruction review requirements of section 112(i)(1) for sources subject to these emissions standards. In addition, this paragraph and Sec. 63.5 of subpart A of this part include other requirements for constructed and reconstructed sources that are or become subject to these emissions standards.

(ii) After the effective date, the requirements in this section and in Sec. 63.5 of subpart A of this part apply to owners or operators who construct a new source or reconstruct a source subject to these emissions standards after December 6, 1994. New or reconstructed sources subject to these emissions standards with an initial startup date before the effective date are not subject to the preconstruction review requirements specified in paragraphs (b) (2) and (3) of this section and Sec. 63.5(d) (3) and (4) and (e) of subpart A of this part.

(2) After the effective date, whether or not an approved permit program is effective in the State in which a source is (or would be) located, no person may construct a new source or reconstruct a source subject to these emissions standards, or reconstruct a source such that the source becomes a source subject to these emissions standards, without obtaining advance written approval from the Administrator in accordance with the procedures specified in paragraph (b)(3) of this section and Sec. 63.5(d) (3) and (4) and (e) of subpart A of this part.

(3) Application for approval of construction or reconstruction. The provisions of paragraph (b)(3) of this section and Sec. 63.5(d) (3) and (4) of subpart A of this part implement section 112(i)(1) of the Act.

(i) General application requirements.

(A) An owner or operator who is subject to the requirements of paragraph (b)(2) of this section shall submit to the Administrator an application for approval of the construction of a new source subject to these emissions standards, the reconstruction of a source subject to these emissions standards, or the reconstruction of a source such that the source becomes a source subject to these emissions standards. The application shall be submitted as soon as practicable before the construction or reconstruction is planned to commence (but not sooner than the effective date) if the construction or reconstruction commences after the effective date. The application shall be submitted as soon as practicable before the initial startup date but no later than 60 days after the effective date if the construction or reconstruction had commenced and the initial startup date had not occurred before the effective date. The application for approval of construction or reconstruction may be used to fulfill the initial notification requirements of paragraph (c)(1)(iii) of this section. The owner or operator may submit the application for approval well in advance of the date construction or reconstruction is planned to commence in order to ensure a timely review by the Administrator and that the planned commencement date will not be delayed.

(B) A separate application shall be submitted for each construction or reconstruction. Each application for approval of construction or reconstruction shall include at a minimum:

(1) The applicant's name and address.

(2) A notification of intention to construct a new source subject to these emissions standards or make any physical or operational change to a source subject to these emissions standards that may meet or has been determined to meet the criteria for a reconstruction, as defined in Sec. 63.2 of subpart A of this part.

(3) The address (i.e., physical location) or proposed address of the source.

(4) An identification of the relevant standard that is the basis of the application.

(5) The expected commencement date of the construction or reconstruction.

(6) The expected completion date of the construction or reconstruction.

(7) The anticipated date of (initial) startup of the source.

(8) The type and quantity of hazardous air pollutants emitted by the source, reported in units and averaging times and in accordance with the test methods specified in the standard, or if actual emissions data are not yet available, an estimate of the type and quantity of hazardous air pollutants expected to be emitted by the source reported in units and averaging times specified. The owner or operator may submit percent reduction information, if the standard is established in terms of percent reduction. However, operating parameters, such as flow rate, shall be included in the submission to the extent that

they demonstrate performance and compliance.

(9) Other information as specified in paragraph (b)(3)(ii) of this section and Sec. 63.5(d)(3) of subpart A of this part.

(C) An owner or operator who submits estimates or preliminary information in place of the actual emissions data and analysis required in paragraphs (b)(3)(i)(B)(8) and (ii) of this section shall submit the actual, measured emissions data and other correct information as soon as available but no later than with the notification of compliance status required in paragraph (c)(2) of this section.

(ii) Application for approval of construction. Each application for approval of construction shall include, in addition to the information required in paragraph (b)(3)(i)(B) of this section, technical information describing the proposed nature, size, design, operating design capacity, and method of operation of the source subject to these emissions standards, including an identification of each point of emission for each hazardous air pollutant that is emitted (or could be emitted) and a description of the planned air pollution control system (equipment or method) for each emission point. The description of the equipment to be used for the control of emissions shall include each control device for each hazardous air pollutant and the estimated control efficiency (percent) for each control device. The description of the method to be used for the control of emissions shall include an estimated control efficiency (percent) for that method. Such technical information shall include calculations of emission estimates in sufficient detail to permit assessment of the validity of the calculations. An owner or operator who submits approximations of control efficiencies under paragraph (b)(3) of this section shall submit the actual control efficiencies as specified in paragraph (b)(3)(i)(C) of this section.

(4) Approval of construction or reconstruction based on prior State preconstruction review. (i) The Administrator may approve an application for construction or reconstruction specified in paragraphs (b)(2) and (3) of this section and Sec. 63.5(d)(3) and (4) of subpart A of this part if the owner or operator of a new or reconstructed source who is subject to such requirement demonstrates to the Administrator's satisfaction that the following conditions have been (or will be) met:

(A) The owner or operator of the new or reconstructed source subject to these emissions standards has undergone a preconstruction review and approval process in the State in which the source is (or would be) located before the effective date and has received a federally enforceable construction permit that contains a finding that the source will meet these emissions standards as proposed, if the source is properly built and operated;

(B) In making its finding, the State has considered factors substantially equivalent to those specified in Sec. 63.5(e)(1) of subpart A of this part.

(ii) The owner or operator shall submit to the Administrator the request for approval of construction or reconstruction no later than the application deadline specified in paragraph (b)(3)(i) of this section. The owner or operator shall include in the request information sufficient for the Administrator's determination. The Administrator will evaluate the owner or operator's request in accordance with the procedures specified in Sec. 63.5 of subpart A of this part. The Administrator may request additional relevant information after the submittal of a request for approval of construction or reconstruction.

(c) Notification requirements. The owner or operator of each source subject to the emissions standards in Sec. 63.362 shall fulfill all notification requirements in Sec. 63.9 of subpart A of this part, according to the applicability in Table 1 of Sec. 63.360, and in this paragraph.

(1) Initial notifications.

(i)(A) If a source that otherwise would be subject to these emissions standards subsequently increases its use of ethylene oxide within any consecutive 12-month period after December 6, 1996, such that the source becomes subject to these emissions standards or other requirements, such source shall be subject to the notification requirements of Sec. 63.9 of subpart A of this part.

(B) Sources subject to these emissions standards may use the application for approval of construction or reconstruction under paragraph (b)(3)(ii) of this section and Sec. 63.5(d) (3) of subpart A of this part, respectively, if relevant to fulfill the initial notification requirements.

(ii) The owner or operator of a new or reconstructed source subject to these emissions standards that has an initial startup date after the effective date and for which an application for approval of construction or reconstruction is required under paragraph (b)(3) of this section and Sec. 63.5(d) (3) and (4) of subpart A of this part shall provide the following information in writing to the Administrator:

(A) A notification of intention to construct a new source subject to these emissions standards, reconstruct a source subject to these emissions standards, or reconstruct a source such that the source becomes a source subject to these emissions standards with the application for approval of construction or reconstruction as specified in paragraph (b)(3)(i)(A) of this section;

(B) A notification of the date when construction or reconstruction was commenced, submitted simultaneously with the application for approval of construction or reconstruction, if construction or reconstruction was commenced before the effective date of these standards;

(C) A notification of the date when construction or reconstruction was commenced, delivered or postmarked not later than 30 days after such date, if construction or reconstruction was commenced after the effective date of these standards;

(D) A notification of the anticipated date of startup of the source, delivered or postmarked not more than 60 days nor less than 30 days before such date; and

(E) A notification of the actual date of initial startup of the source, delivered or postmarked within 15 calendar days after that date.

(iii) After the effective date, whether or not an approved permit program is effective in the State in which a source subject to these emissions standards is (or would be) located, an owner or operator who intends to construct a new source subject to these emissions standards or reconstruct a source subject to these emissions standards, or reconstruct a source such that it becomes a source subject to these emissions standards, shall notify the Administrator in writing of the intended construction or reconstruction. The notification shall be submitted as soon as practicable before the construction or reconstruction is planned to commence (but no sooner than the effective date of these standards) if the construction or reconstruction commences after the effective date of the standard. The notification shall be submitted as soon as practicable before the initial startup date but no later than 60 days after the effective date of this standard if the construction or reconstruction had commenced and the initial startup date has not occurred before the standard's effective date. The notification shall include all the information required for an application for approval of construction or reconstruction as specified in paragraph (b)(3) of this section and Sec. 63.5(d)(3) and (4) of subpart A of this part. For sources subject to these emissions standards, the application for approval of construction or reconstruction may be used to fulfill the initial notification requirements of Sec. 63.9 of subpart A of this part.

(2) If an owner or operator of a source subject to these emissions standards submits estimates or preliminary information in the application for approval of construction or reconstruction required in paragraph (b)(3)(ii) of this section and Sec. 63.5(d)(3) of subpart A of this part, respectively, in place of the actual emissions data or control efficiencies required in paragraphs (b)(3)(i)(B)(8) and (ii) of this section, the owner or operator shall submit the actual emissions data and other correct information as soon as available but no later than with the initial notification of compliance status.

(3) The owner or operator of any existing sterilization facility subject to this subpart shall also include the amount of ethylene oxide used during the previous consecutive 12-month period in the initial notification report required by Sec. 63.9(b)(2) and (3) of subpart A of this part. For new sterilization facilities subject to this subpart, the amount of ethylene oxide used shall be an estimate of expected use during the first consecutive 12-month period of operation.

VI. WORK PRACTICE REQUIREMENTS.

 # 014 [25 Pa. Code §127.12b]
Plan approval terms and conditions.

The facility shall be:

a. Operated in such a manner as not to cause air pollution as that term is defined in 25 Pa. Code § 121.1;

b. Operated and maintained in a manner consistent with good operating and maintenance practices;

c. Operated and maintained in accordance with practices based on the "manufacturer's specifications;" and

APPENDIX II

Example Field Sheets

Analyzer Calibration Data Sheet

Company	
Location	
Source	
Date	
Time	

						DIRECT CALIBRATIONS							
Analyzer Type	Zero	Gas 1 Value	Gas 2 Value	Gas 3 Value	Gas 4 Value	Gas 5 Value	Gas 6 Value	Gas 7 Value	Gas 8 Value	Gas 9 Value	Gas 10 Value	Gas 11 Value	Gas 12 Value
Time													

						Initial Bias							
Analyzer Type	Zero	Bias 1 Value	Bias 2 Value	Bias 3 Value	Bias 4 Value	Bias 5 Value	Bias 6 Value	Bias 7 Value	Bias 8 Value	Bias 9 Value	Bias 10 Value	Bias 11 Value	Bias 12 Value
Time													

			RUN ______					
Start:				Stop:				
			Bias					
Analyzer Type	Zero	Bias 1 Value	Bias 2 Value	Bias 3 Value	Bias 4 Value	Bias 5 Value	Bias 6 Value	
								HL
								HL
								HL
								HL
								HL
								HL
								HL
Time								HL

Channel Inputs	
A	______
B	______
C	______
D	______
E	______
F	______
G	______
H	______
I	______
J	______
K	______
L	______
M	

RUN ______								
Start:				Stop:				
Bias								
Analyzer Type	Zero	Bias 1 Value ____	Bias 2 Value ____	Bias 3 Value ____	Bias 4 Value ____	Bias 5 Value ____	Bias 6 Value ____	
								HL
								HL
								HL
								HL
								HL
								HL
								HL
Time								HL

RUN ______								
Start:				Stop:				
Bias								
Analyzer Type	Zero	Bias 1 Value ____	Bias 2 Value ____	Bias 3 Value ____	Bias 4 Value ____	Bias 5 Value ____	Bias 6 Value ____	
								HL
								HL
								HL
								HL
								HL
								HL
								HL
Time								HL

RUN ______								
Start:				Stop:				
Bias								
Analyzer Type	Zero	Bias 1 Value ____	Bias 2 Value ____	Bias 3 Value ____	Bias 4 Value ____	Bias 5 Value ____	Bias 6 Value ____	
								HL
								HL
								HL
								HL
								HL
								HL
								HL
Time								HL

Analyzer Response Test

Analyzer Make
Analyzer Model
Analyzer Serial #

Methods 7E, 3A, 10
Use Low and High Gases and perform during initial system bias

Perform 2 runs as follows: Run the Low gas. Record the time it takes the Low gas to reach 95% of the value. Repeat the process for the High gas. The response time is dictated by the longest run seen to achieve 95% of the gas value used.

Run #	Gas Type	Response Time

System Response Time

Method 2 FLOW DATA SHEET

Project No. ______________ Site Location ______________ MB / Manometer # ______________ Operator(s) ______________

Proj. Name ______________ Unit/Location ______________ Pitot Tube / Probe ID # ______________ Baro. Pressure ______________

(circle one)

Stack ID ______________

Start Time		Stop Time	
Date	Leak Check	WB	
	PRE		
RUN #	POST	DB	
	STATIC		
		Stack	
Real Time	Traverse Pt.	Delta P	Temp. (°F)

Start Time		Stop Time	
Date	Leak Check	WB	
	PRE		
RUN #	POST	DB	
	STATIC		
		Stack	
Real Time	Traverse Pt.	Delta P	Temp. (°F)

Start Time		Stop Time	
Date	Leak Check	WB	
	PRE		
RUN #	POST	DB	
	STATIC		
		Stack	
Real Time	Traverse Pt.	Delta P	Temp. (°F)

Start Time		Stop Time	
Date	Leak Check	WB	
	PRE		
RUN #	POST	DB	
	STATIC		
		Stack	
Real Time	Traverse Pt.	Delta P	Temp. (°F)

Method 4 MOISTURE DATA SHEET

Project # ____________________
Proj. Name ____________________
Date ____________________
Site Loc. ____________________
Unit/Loc. ____________________

Meter Box # ____________________
Delta Y @ ____________________
Delta H @ ____________________
MB Pump # ____________________
Stack ID ____________________

Operator(s) ____________________
Run ____ Baro. Press. ____________________
Run ____ Baro. Press. ____________________
Run ____ Baro. Press. ____________________

RUN #	MOISTURE TRAIN					Start Time		Stop Time		Impingers ICED ?	
	Sampling Time	Dry Gas Meter				EXIT Impinger Temp.(°F)	Pump Vacuum ("Hg)				
Real Time		VOLUME (ft^3)	Delta H	In.Temp. (°F)	Out Temp.(°F)						

Train Leak Check			
PRE		POST	
CFM@	VAC	CFM@	VAC
@		@	
Imp. #	Initial	Final	Diff.
1			
2			
3			
4			
5			
6			
7			
8			
9			
T			

RUN #	MOISTURE TRAIN					Start Time		Stop Time		Impingers ICED ?	
	Sampling Time	Dry Gas Meter				EXIT Impinger Temp.(°F)	Pump Vacuum ("Hg)				
Real Time		VOLUME (ft^3)	Delta H	In.Temp. (°F)	Out Temp.(°F)						

Train Leak Check			
PRE		POST	
CFM@	VAC	CFM@	VAC
@		@	
Imp. #	Initial	Final	Diff.
1			
2			
3			
4			
5			
6			
7			
8			
9			
T			

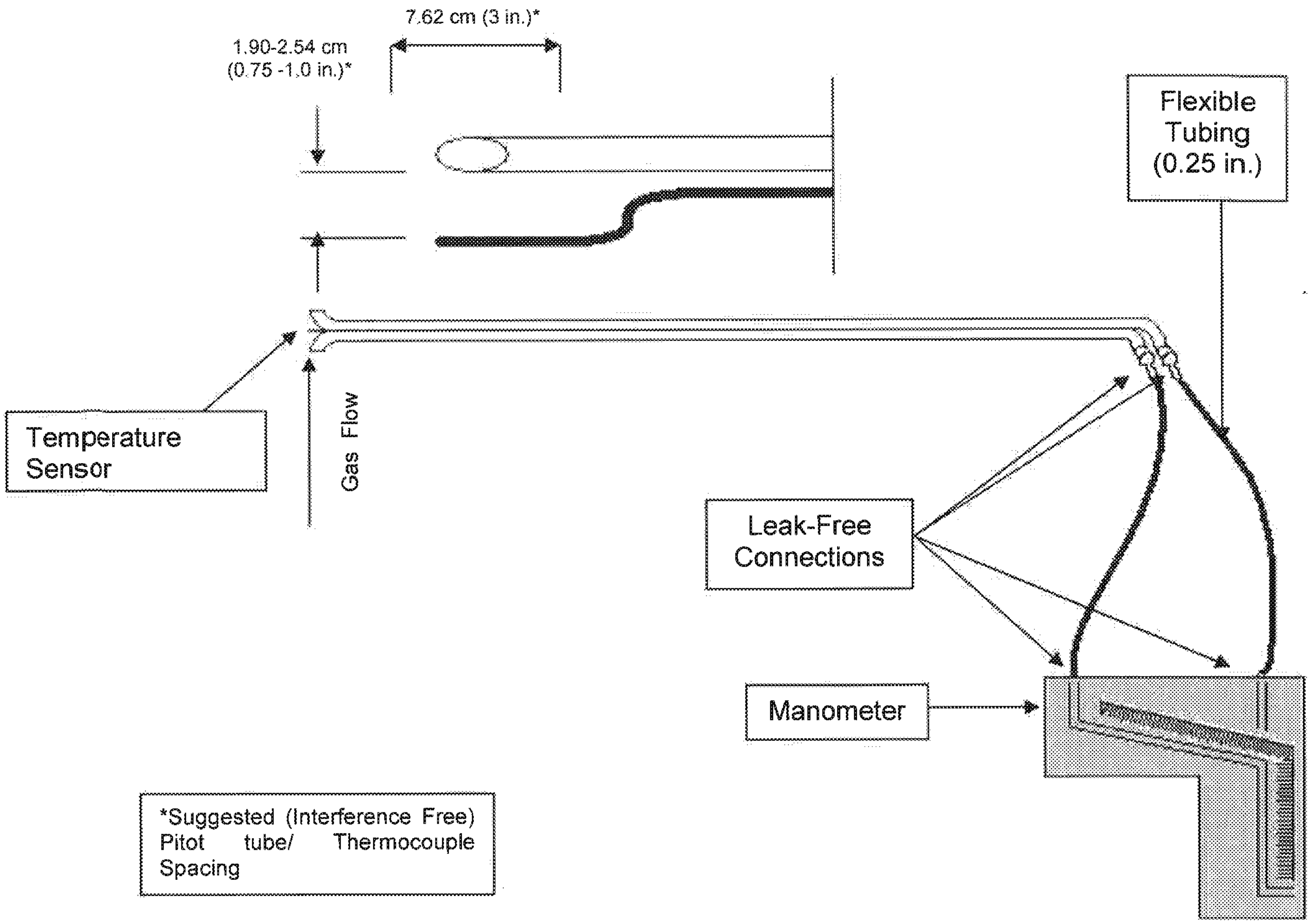
RUN #	MOISTURE TRAIN					Start Time		Stop Time		Impingers ICED ?	
	Sampling Time	Dry Gas Meter				EXIT Impinger Temp.(°F)	Pump Vacuum ("Hg)				
Real Time		VOLUME (ft^3)	Delta H	In.Temp. (°F)	Out Temp.(°F)						

Train Leak Check			
PRE		POST	
CFM@	VAC	CFM@	VAC
@		@	
Imp. #	Initial	Final	Diff.
1			
2			
3			
4			
5			
6			
7			
8			
9			
T			

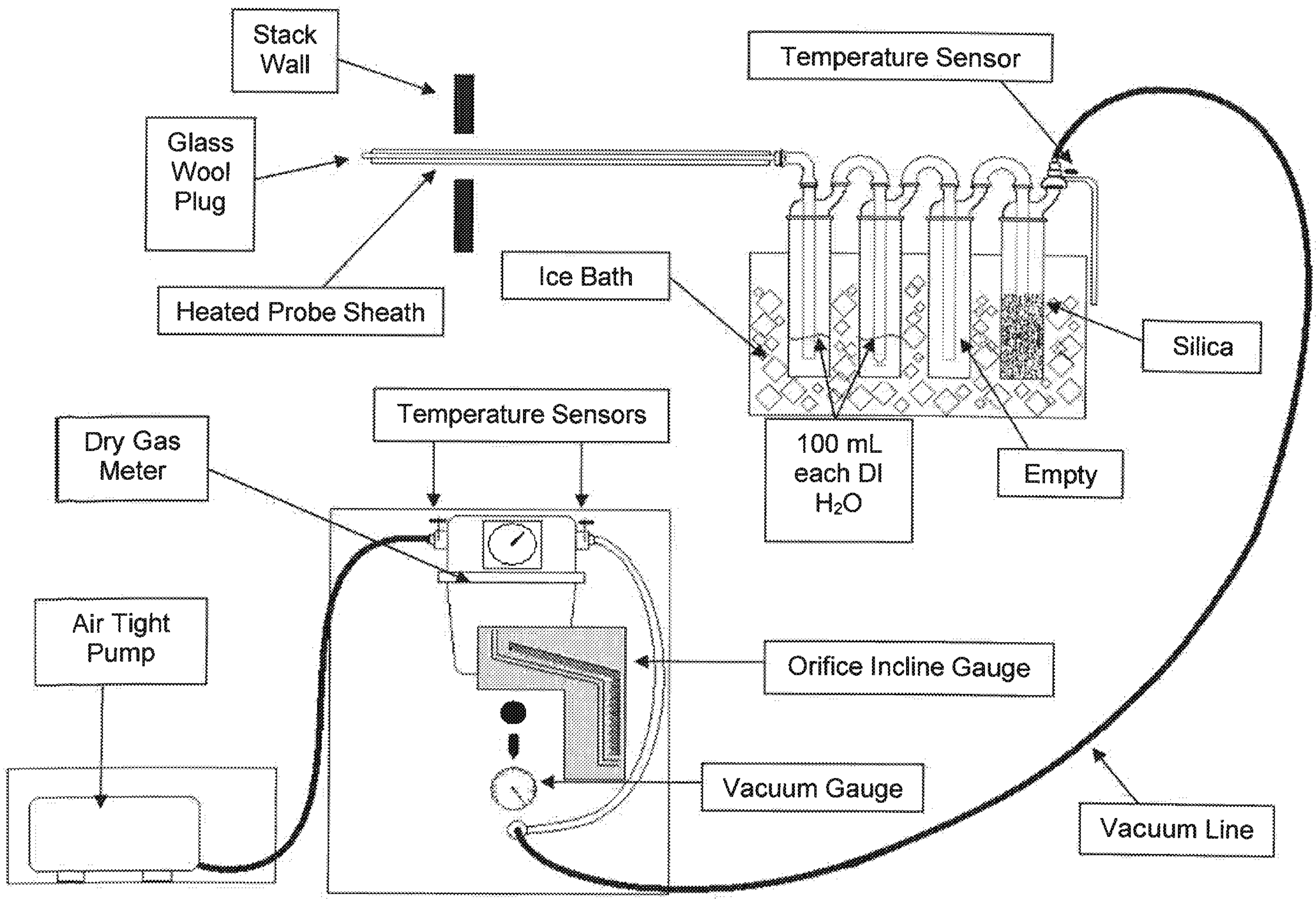
APPENDIX III

Sampling Train Diagrams

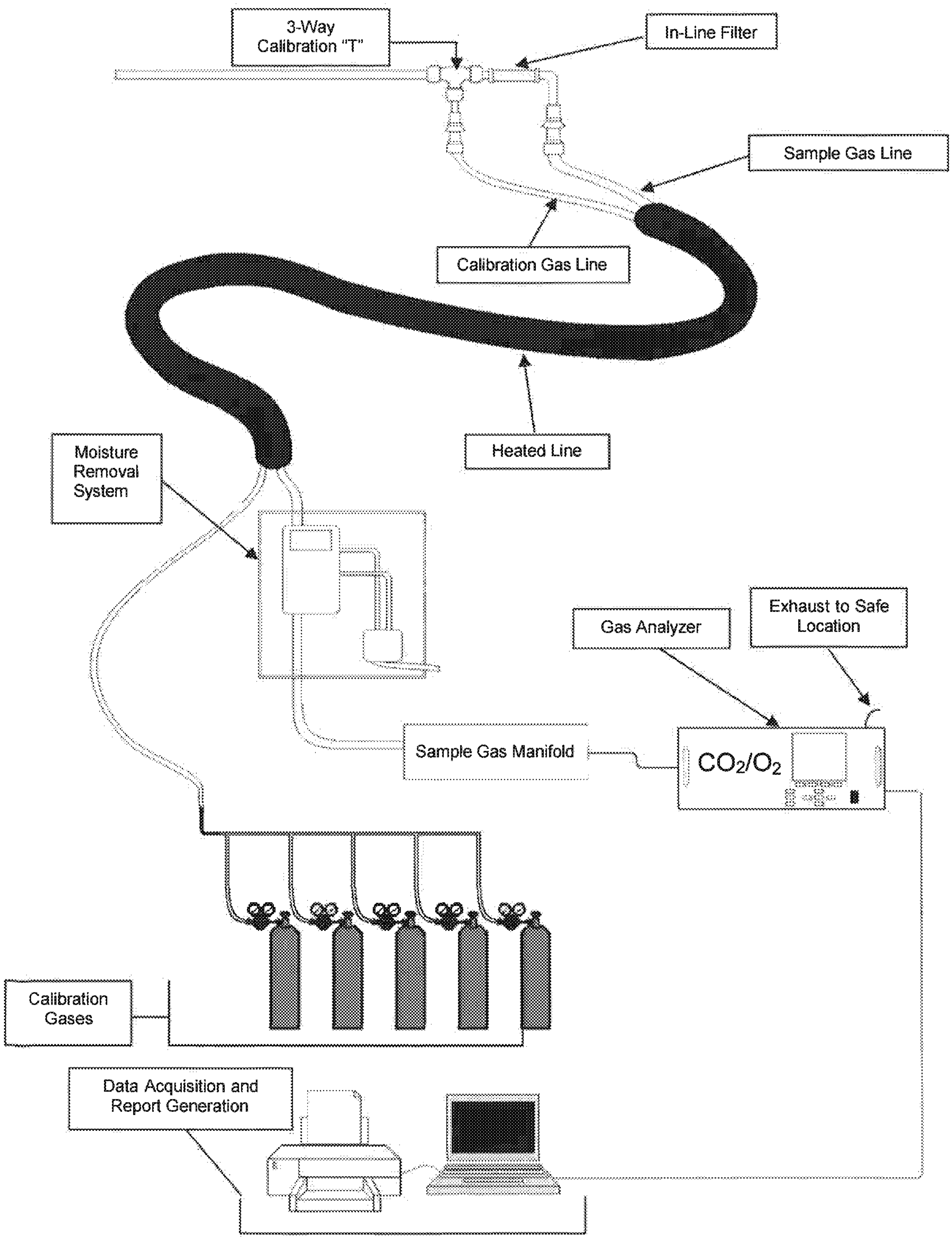
U.S. EPA Method 2- Type S Pitot Tube Manometer Assembly



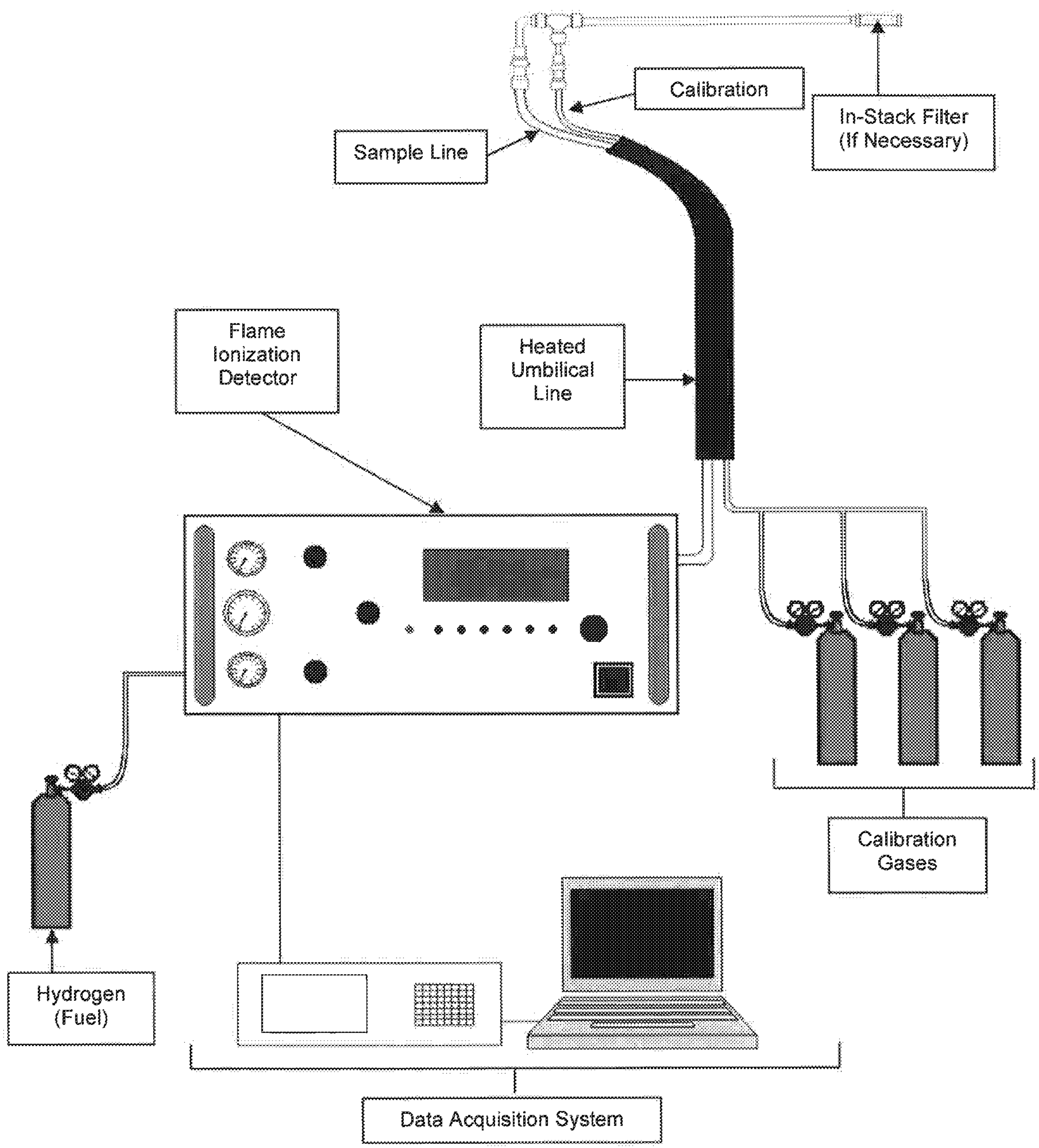
U.S. EPA Method 4- Moisture Content Sample Train Diagram



U.S. EPA Method 3A Extractive Gaseous Sampling Diagram



U.S. EPA Method 25A – Total Gaseous Organic Compound Sample Train



APPENDIX B

EMISSION CALCULATIONS

STERILIZATION CHAMBER

STERILIZATION RUN 1
CHAMBER 7 CYCLE 1
15-Dec-20
0836-0858

Chamber 7 Conditions @ First Evacuation Cycle

PV=nRT >>> n=PV/RT

P	=	[redacted]	psia	=	[redacted]	Pa	
V	=	3600	ft^3	=	101.941	m^3	
R	=	8.31446	m3 Pa/mol k				
T	=	[redacted]	deg F	=	[redacted]	deg K	[redacted]
			n	=	3398.61	mol pre-charge gas in chamber	

ETO Delivered to Chamber 7

W_C	=	[redacted]	lbs ETO charged
	=	[redacted]	volume fraction EtO in gas cylinder
W_C	=	[redacted]	g ETO charged
W_C	=	[redacted]	mol ETO charged

Chamber 7 During Exposure

	3398.61	mol pre-charge gas in chamber
+	[redacted]	mol ETO charged
		total mol ETO solution in chamber
	[redacted]	mol pre-charge gas / mol ETO solution in chamber

Chamber 7 Conditions After First Evacuation

PV=nRT >>> n=PV/RT

P	=	[redacted]	psia	=	[redacted]	Pa	
V	=	3600	ft^3	=	101.941	m^3	
R	=	8.31446	m3 Pa/mol k				
T	=	[redacted]	deg F	=	[redacted]	deg K	[redacted]
			n	=	419.865	mol ETO solution remaining in chamber	

ETO Remaining in Chamber 7 After First Evacuation

		419.865	mol ETO solution remaining in chamber
	x	[redacted]	mol pre-charge gas / mol ETO solution in chamber
			mol pre-charge gas remaining in chamber
		419.865	mol ETO solution remaining in chamber
	-	[redacted]	mol pre-charge gas remaining in chamber
W_R	=	[redacted]	mol ETO remaining in chamber

Chamber 7 ETO Delivered to Peak Shave/Cat Ox Inlet

		[redacted]	mol ETO charged, W_c
	-	[redacted]	mol ETO remaining in chamber, W_R
W_I	=	[redacted]	mol ETO delivered to inlet
W_I	=	[redacted]	g ETO delivered to inlet
W_I	=	[redacted]	lbs ETO delivered to inlet

ETO at Cat Ox Outlet

C = C_{wet} / ((100 - B_{ws}) / 100)

C_{wet} = 0.73 ppmv, wet
B_{ws} = 1.25971 %

C = 0.73558 ppmv, dry

$EtO_{lb/hr}$ = C * Flowrate * MW * 60 min/hr / 385.3 scf/lb-mol * 10^-6

C = 0.73558 ppmv, dry
Flowrate = 15727 dscfm
MW = 44.052 g/mol

$EtO_{lb/hr}$ = 0.07936 lb/hr

W_O = C x V x (MW/SV) x (1/10^6)

C = 0.735581 ppmv, dry
V = 350364 std. cubic feet = 9921201 liters
MW = 44.052 g/mol
SV = 24.05 l/mol

W_O = 13.3673 g ETO outlet

Cat Ox Efficiency

%EFF = $((W_I-W_O)/W_I)*100$

W_I = 60972.6 g ETO delivered to inlet
W_O = 13.3673 g ETO outlet

%EFF = 99.97808

STERILIZATION RUN 2
CHAMBER 7 CYCLE 1
15-Dec-20
1310-1332

Chamber 7 Conditions @ First Evacuation Cycle

PV=nRT >>> n=PV/RT

P	=	[redacted]	psia	=	[redacted]	Pa	
V	=	3600	ft^3	=	101.941	m^3	
R	=	8.314462	m3 Pa/mol k				
T	=	[redacted]	deg F	=	[redacted]	deg K	[redacted]
			n	=	3346.72	mol pre-charge gas in chamber	

ETO Delivered to Chamber 7

W_C	=	[redacted]	lbs ETO charged
	=	[redacted]	volume fraction EtO in gas cylinder
W_C	=	[redacted]	g ETO charged
W_C	=	[redacted]	mol ETO charged

Chamber 7 During Exposure

	3346.720556	mol pre-charge gas in chamber
+	[redacted]	mol ETO charged
	4942.557097	total mol ETO solution in chamber
	0.677123297	mol pre-charge gas / mol ETO solution in chamber

Chamber 7 Conditions After First Evacuation

PV=nRT >>> n=PV/RT

P	=	[redacted]	psia	=	[redacted]	Pa	
V	=	3600	ft^3	=	101.941	m^3	
R	=	8.314462	m3 Pa/mol k				
T	=	[redacted]	deg F	=	[redacted]	deg K	[redacted]
			n	=	393.379	mol ETO solution remaining in chamber	

ETO Remaining in Chamber 7 After First Evacuation

		393.3788901	mol ETO solution remaining in chamber
	x	[redacted]	mol pre-charge gas / mol ETO solution in chamber
			mol pre-charge gas remaining in chamber
		393.3788901	mol ETO solution remaining in chamber
	-	[redacted]	mol pre-charge gas remaining in chamber
W_R	=	[redacted]	mol ETO remaining in chamber

Chamber 7 ETO Delivered to Peak Shave/Cat Ox Inlet

		[redacted]	mol ETO charged, W_c
	-	[redacted]	mol ETO remaining in chamber, W_R
W_I	=	[redacted]	mol ETO delivered to inlet
W_I	=	[redacted]	g ETO delivered to inlet
W_I	=	[redacted]	lbs ETO delivered to inlet

ETO at Cat Ox Outlet

C = C_{wet} **/ ((100 - B_{ws}) / 100)**

C_{wet}	=	0.79	ppmv, wet
B_{ws}	=	2.152261056	%
C	=	0.80550	ppmv, dry

$EtO_{lb/hr}$ = C * Flowrate * MW * 60 min/hr / 385.3 scf/lb-mol * 10^-6

C	=	0.80550	ppmv, dry
Flowrate	=	15663	dscfm
MW	=	44.052	g/mol
$EtO_{lb/hr}$	=	0.086549767	lb/hr

W_O = C x V x (MW/SV) x (1/10^6)

C	=	0.8055	ppmv, dry		
V	=	352188.43	std. cubic feet	=	9972867 liters
MW	=	44.052	g/mol		
SV	=	24.05	l/mol		
W_O	=	14.7141823	g ETO outlet		

Cat Ox Efficiency

%EFF = $((W_I - W_O)/W_I)*100$

W_I	=	64704.61996	g ETO delivered to inlet
W_O	=	14.7141823	g ETO outlet
%EFF	=	**99.97726**	

STERILIZATION RUN 3
CHAMBER 7 CYCLE 1
15-Dec-20
1709-1730

Chamber 7 Conditions @ First Evacuation Cycle

PV=nRT >>> n=PV/RT

P	=	[redacted]	psia	=	[redacted]	Pa	
V	=	3600	ft^3	=	101.941	m^3	
R	=	8.31446	m3 Pa/mol k				
T	=	[redacted]	deg F	=	[redacted]	deg K	[redacted]
			n	=	3372.66	mol pre-charge gas in chamber	

ETO Delivered to Chamber 7

W_C	=	[redacted]	lbs ETO charged
	=	[redacted]	volume fraction EtO in gas cylinder
W_C	=	[redacted]	g ETO charged
W_C	=	[redacted]	mol ETO charged

Chamber 7 During Exposure

3372.66 mol pre-charge gas in chamber
+ [redacted] mol ETO charged
4937.61 total mol ETO solution in chamber

0.68306 mol pre-charge gas / mol ETO solution in chamber

Chamber 7 Conditions After First Evacuation

PV=nRT >>> n=PV/RT

P	=	[redacted]	psia	=	[redacted]	Pa	
V	=	3600	ft^3	=	101.941	m^3	
R	=	8.31446	m3 Pa/mol k				
T	=	[redacted]	deg F	=	[redacted]	deg K	[redacted]
			n	=	472.935	mol ETO solution remaining in chamber	

ETO Remaining in Chamber 7 After First Evacuation

472.935 mol ETO solution remaining in chamber
x [redacted] mol pre-charge gas / mol ETO solution in chamber
mol pre-charge gas remaining in chamber

472.935 mol ETO solution remaining in chamber
- [redacted] mol pre-charge gas remaining in chamber
W_R = [redacted] mol ETO remaining in chamber

Chamber 7 ETO Delivered to Peak Shave/Cat Ox Inlet

		[redacted]	mol ETO charged, W_c
	-	[redacted]	mol ETO remaining in chamber, W_R
W_I	=	[redacted]	mol ETO delivered to inlet
W_I	=	[redacted]	g ETO delivered to inlet
W_I	=	[redacted]	lbs ETO delivered to inlet

ETO at Cat Ox Outlet

$$C = C_{wet} / ((100 - B_{ws}) / 100)$$

C_{wet}	=	0.77	ppmv, wet
B_{ws}	=	2.0345	%
C	=	0.7836	ppmv, dry

$$EtO_{lb/hr} = C * Flowrate * MW * 60 \text{ min/hr} / 385.3 \text{ scf/lb-mol} * 10^{-6}$$

C	=	0.7836	ppmv, dry
Flowrate	=	18129.3	dscfm
MW	=	44.052	g/mol
$EtO_{lb/hr}$	=	0.09745	lb/hr

$$W_O = C \times V \times (MW/SV) \times (1/10^6)$$

C	=	0.7836	ppmv, dry			
V	=	388643	std. cubic feet	=	1.1E+07	liters
MW	=	44.052	g/mol			
SV	=	24.05	l/mol			
W_O	=	15.7959	g ETO outlet			

Cat Ox Efficiency

$$\%EFF = ((W_I - W_O)/W_I)*100$$

W_I	=	62336	g ETO delivered to inlet
W_O	=	15.7959	g ETO outlet

%EFF = 99.97466

STACK FLOWRATE CALCULATOR

Customer Name:	B Braun	Date	12/15/20
Location:	Allentown, PA	Moisture Time	0836-0906
Source:	CatOx Outlet	Run No.	1

INPUT DATA	
Beginning Meter Setting (cubic feet):	38.785
Ending Meter Setting (cubic feet):	62.520
Total Metered Volume (cubic feet) [Vm]:	23.735
Water Caught (grams) [Wc]	6.5
Stack Pressure ("H2O) [Ps]	-2.7
Barometric Pressure ("HG) [Pb]	30.31
Carbon Dioxide (%) [CO2]	0.49
Oxygen (%) [O2]	20.31
Delta H ("H2O) [H]	2.00
Pitot Tube Factor [Cp]	0.84
Meter Correction Factor [Y]	1.014
Stack Inside Diameter (in) [ID]	29.5
Stack Cross-Section (square feet) [CSA]	4.746

OUTPUT DATA	
Meter Volume (Dry cubic feet @stp) [Vms]	**24.033**
Moisture Volume (cubic feet) [Vws]	0.307
Moisture (% @ stp) [Bws]	**1.26**
Dry Molecular Weight (lb/lb-Mol) [MWd]	28.89
Wet Molecular Weight (lb/lb-Mol) [MWw]	28.75
Absolute Stack Pressure ("Hg) [Pa]	30.11
Stack Gas Velocities (feet/second)	
Actual (ft/sec) [Vsa]:	67.41
Standard, Average (SFS) [Vss]:	55.93
Stack Flowrate (cubic feet/minute)	
Average Actual (ACFM):	19196
Standard Average (SCFM):	15928
Dry, Standard Avg (DSCFM):	15727

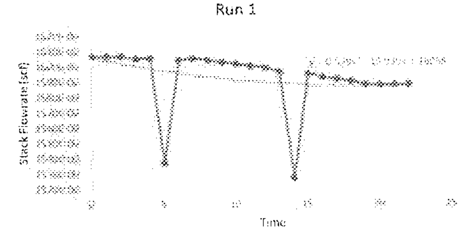
Impinger Weights		
Final Wt	**Initial Wt**	**Gain**
771.1	734.0	37.1
691.2	726.0	-34.8
658.1	657.3	0.8
963.1	959.7	3.4
Water Caught (gms)		**6.5**

STP = Standard Conditions = 68 Deg F (A)
29.92 "Hg (B)

Equations
CSA = ID^2 / 183.3465
Vms = (17.71)(Y)(Vm)(((H / 13.6) + Pb) / (Tm + 460))
Vws = Wc / 21.2
Bws = (100)(Vws) / (Vms + Vws)
MWd = (CO2)(0.44) + (O2)(0.32) + (100 - (CO2 + O2))(.28)
MWw = (Bws)(0.18) + ((MWd)(100 - Bws) / 100)
Pa = Pb + (Ps1 / 13.6)
Vsa = (((Ts + 460) / (((Ps / 13.6) + Pb)(MWw)))^0.5)(Cp)(dP)(85.49)
Vss = (((Vsa)(((Ps / 13.6) + Pb) / (Ts + 460)))(17.71 / 2)
ACFM = (Vsa)(CSA)(60 sec/min)
SCFM = (Vss)(CSA)(60 sec/min)
DSCFM = ((100 - Bws)/ 100)(SCFM)

Minute	Flow Time	Delta P ("H2O)	Stack Temp (Deg F)	Square Root Delta P	Gas Meter Temps (deg F) In	Gas Meter Temps (deg F) Out	Stack Velocities (feet/sec) Ave. Actual (Vsa)	Stack Velocities (feet/sec) Std. Actual (Vss)	Stack Flow Rate Ave. Actual (acfm)	Stack Flow Rate Std. Ave. (scfm)
0	0836	1.2	174	1.095	73	73	67.32	56.42	19170.68	16067.65
1	0837	1.2	174	1.095	76	73	67.32	56.42	19170.68	16067.65
2	0838	1.2	174	1.095	81	73	67.32	56.42	19170.68	16067.65
3	0839	1.2	175	1.095	85	74	67.37	56.38	19185.79	16055.00
4	0840	1.2	175	1.095	89	75	67.37	56.38	19185.79	16055.00
5	0841	1.1	175	1.049	91	76	64.50	53.98	18368.99	15371.49
6	0842	1.2	176	1.095			67.42	56.33	19200.89	16042.37
7	0843	1.2	175	1.095			67.37	56.38	19185.79	16055.00
8	0844	1.2	176	1.095			67.42	56.33	19200.89	16042.37
9	0845	1.2	177	1.095			67.47	56.29	19215.98	16029.77
10	0846	1.2	178	1.095			67.53	56.24	19231.06	16017.21
11	0847	1.2	179	1.095			67.58	56.20	19246.12	16004.67
12	0848	1.2	180	1.095			67.63	56.15	19261.18	15992.16
13	0849	1.2	182	1.095			67.74	56.07	19291.25	15967.23
14	0850	1.1	183	1.049			64.91	53.64	18484.34	15275.57
15	0851	1.2	183	1.095			67.79	56.02	19306.27	15954.81
16	0852	1.2	185	1.095			67.90	55.94	19336.27	15930.05
17	0853	1.2	186	1.095			67.95	55.89	19351.25	15917.72
18	0854	1.2	187	1.095			68.00	55.85	19366.22	15905.41
19	0855	1.2	189	1.095			68.11	55.76	19396.13	15880.89
20	0856	1.2	189	1.095			68.11	55.76	19396.13	15880.89
21	0857	1.2	189	1.095			68.11	55.76	19396.13	15880.89
22	0858	1.2	189	1.095			68.11	55.76	19396.13	15880.89
23										
24										
Averages:		1.191	180 [Ts]	1.091 [dP]		78.3 [Tm]	67.41	55.93	19196.29	15927.93

Run 1



y = 0.539x^2 - 19.939x + 16058
F(x) = (0.539/3)x^3 - (19.939/2)x^2 + 16058x +c

x	F(x)		
0	=(0.539/3)*0^3 - (19.939/2)*0^2 + 16058*0 + c	=	0.00
22	=(0.539/3)*22^3 - (19.939/2)*22^2 + 16058*22 + c	=	350,363.85
Area	= F(22) - F(0)	=	**350,363.85** V (scf)*

*Calculated in accordance with Subpart O by integrating area under curve plotted using volumetric flowrate vs time.

STACK FLOWRATE CALCULATOR

Customer Name:	B Braun	Date	12/15/20
Location:	**Allentown, PA**	Moisture Time	1310-1340
Source:	**CatOx Outlet**	Run No.	2

INPUT DATA	
Beginning Meter Setting (cubic feet):	131.155
Ending Meter Setting (cubic feet):	155.020
Total Metered Volume (cubic feet) [Vm]:	23.9
Water Caught (grams) [Wc]	10.80
Stack Pressure ("H2O) [Ps]	**-2.8**
Barometric Pressure ("HG) [Pb]	**30.31**
Carbon Dioxide (%) [CO2]	**0.39**
Oxygen (%) [O2]	**20.33**
Delta H ("H2O) [H]	2.00
Pitot Tube Factor [Cp]	0.84
Meter Correction Factor [Y]	1.014
Stack Inside Diameter (in) [ID]	29.5
Stack Cross-Section (square feet) [CSA]	4.746

OUTPUT DATA	
Meter Volume (Dry cubic feet @stp) [Vms]	**23.160**
Moisture Volume (cubic feet) [Vws]	0.509
Moisture (% @ stp) [Bws]	**2.15**
Dry Molecular Weight (lb/lb-Mol) [MWd]	28.88
Wet Molecular Weight (lb/lb-Mol) [MWw]	28.64
Absolute Stack Pressure ("Hg) [Pa]	30.10
Stack Gas Velocities (feet/second)	
Actual (ft/sec) [Vsa]:	67.83
Standard, Average (SFS) [Vss]:	56.21
Stack Flowrate (cubic feet/minute)	
Average Actual (ACFM):	19317
Standard Average (SCFM):	16008
Dry, Standard Avg (DSCFM):	**15663**

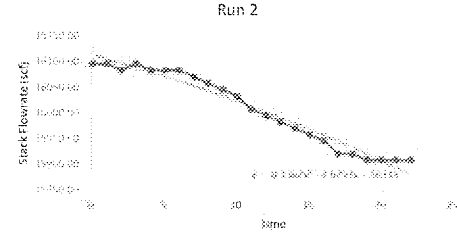
Impinger Weights		
Final Wt	**Initial Wt**	**Gain**
776.7	773.6	3.1
692.2	690.6	1.6
658.5	657.3	1.2
970.9	966.0	4.9
Water Caught (gms)		10.8

STP = Standard Conditions = 68 Deg F (A)
29.92 "Hg (B)

Equations
CSA = ID^2 / 183.3465
Vms = (17.71)(Y)(Vm)(((H / 13.6) + Pb) / (Tm + 460))
Vws = Wc / 21.2
Bws = (100)(Vws) / (Vms + Vws)
MWd = (CO2)(0.44) + (O2)(0.32) + (100 - (CO2 + O2))(.28)
MWw = (Bws)(0.18) + ((MWd)(100 - Bws) / 100)
Pa = Pb + (Ps1 / 13.6)
Vsa = (((Ts + 460) / (((Ps / 13.6) + Pb)(MWw)))^0.5)(Cp)(dP)(85.49)
Vss = (((Vsa)(((Ps / 13.6) + Pb) / (Ts + 460)))(17.71 / 2)
ACFM = (Vsa)(CSA)(60 sec/min)
SCFM = (Vss)(CSA)(60 sec/min)
DSCFM = ((100 - Bws)/ 100)(SCFM)

Minute	Flow Time	Delta P ("H2O)	Stack Temp (Deg F)	Square Root Delta P	Gas Meter Temps (deg F) In	Gas Meter Temps (deg F) Out	Stack Velocities (feet/sec) Ave. Actual (Vsa)	Stack Velocities (feet/sec) Std. Actual (Vss)	Stack Flow Rate Ave. Actual (acfm)	Stack Flow Rate Std. Ave. (scfm)
0	1310	1.2	174	1.095	97	96	67.45	56.52	19210.41	16097.02
1	1311	1.2	174	1.095	103	96	67.45	56.52	19210.41	16097.02
2	1312	1.2	175	1.095	107	96	67.51	56.48	19225.55	16084.34
3	1313	1.2	174	1.095	110	96	67.45	56.52	19210.41	16097.02
4	1314	1.2	175	1.095	111	97	67.51	56.48	19225.55	16084.34
5	1315	1.2	175	1.095	112	98	67.51	56.48	19225.55	16084.34
6	1316	1.2	175	1.095			67.51	56.48	19225.55	16084.34
7	1317	1.2	176	1.095			67.56	56.43	19240.68	16071.69
8	1318	1.2	177	1.095			67.61	56.39	19255.80	16059.07
9	1319	1.2	178	1.095			67.67	56.35	19270.91	16046.48
10	1320	1.2	179	1.095			67.72	56.30	19286.01	16033.92
11	1321	1.2	181	1.095			67.83	56.21	19316.17	16008.89
12	1322	1.2	182	1.095			67.88	56.17	19331.23	15996.41
13	1323	1.2	183	1.095			67.93	56.13	19346.28	15983.97
14	1324	1.2	184	1.095			67.98	56.08	19361.31	15971.56
15	1325	1.2	185	1.095			68.04	56.04	19376.34	15959.17
16	1326	1.2	186	1.095			68.09	56.00	19391.36	15946.81
17	1327	1.2	188	1.095			68.20	55.91	19421.35	15922.18
18	1328	1.2	188	1.095			68.20	55.91	19421.35	15922.18
19	1329	1.2	189	1.095			68.25	55.87	19436.33	15909.91
20	1330	1.2	189	1.095			68.25	55.87	19436.33	15909.91
21	1331	1.2	189	1.095			68.25	55.87	19436.33	15909.91
22	1332	1.2	189	1.095			68.25	55.87	19436.33	15909.91
23										
24										
Averages:		1.200	181 [Ts]	1.095 [dP]		101.6 [Tm]	67.83	56.21	19317.28	16008.28

Run 2



y = -0.1302x^2 - 7.6754x + 16114
F(x) = -(0.1302/3)x^3 - (7.6754/2)x^2 + 16114x +c

x	F(x)		
0	= -(0.1302/3)*0^3 - (7.6754/2)*0^2 + 16114*0 + c	=	0.00
22	= -(0.1302/3)*22^3 - (7.6754/2)*22^2 + 16114*22 + c	=	352,188.43
Area	= F(22) - F(0)	=	**352,188.43** V (scf)*

*Calculated in accordance with Subpart O by integrating area under curve plotted using volumetric flowrate vs time.

STACK FLOWRATE CALCULATOR

Customer Name:	B Braun	Date	12/15/20
Location:	**Allentown, PA**	Moisture Time	1709-1739
Source:	**CatOx Outlet**	Run No.	3

INPUT DATA	
Beginning Meter Setting (cubic feet):	189.380
Ending Meter Setting (cubic feet):	213.212
Total Metered Volume (cubic feet) [Vm]:	23.8
Water Caught (grams) [Wc]	10.30
Stack Pressure ("H2O) [Ps]	-3.0
Barometric Pressure ("HG) [Pb]	30.35
Carbon Dioxide (%) [CO2]	0.38
Oxygen (%) [O2]	20.32
Delta H ("H2O) [H]	2.00
Pitot Tube Factor [Cp]	0.84
Meter Correction Factor [Y]	1.014
Stack Inside Diameter (in) [ID]	29.5
Stack Cross-Section (square feet) [CSA]	4.746

OUTPUT DATA	
Meter Volume (Dry cubic feet @stp) [Vms]	23.395
Moisture Volume (cubic feet) [Vws]	0.486
Moisture (% @ stp) [Bws]	2.03
Dry Molecular Weight (lb/lb-Mol) [MWd]	28.87
Wet Molecular Weight (lb/lb-Mol) [MWw]	28.65
Absolute Stack Pressure ("Hg) [Pa]	30.13
Stack Gas Velocities (feet/second)	
Actual (ft/sec) [Vsa]:	78.21
Standard, Average (SFS) [Vss]:	64.98
Stack Flowrate (cubic feet/minute)	
Average Actual (ACFM):	22272
Standard Average (SCFM):	18506
Dry, Standard Avg (DSCFM):	18129

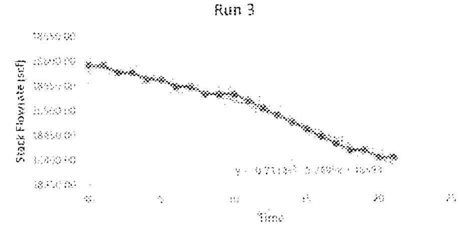
Impinger Weights		
Final Wt	**Initial Wt**	**Gain**
779.6	776.7	2.9
693.7	692.2	1.5
659.7	658.5	1.2
975.6	970.9	4.7
Water Caught (gms)		10.3

STP = Standard Conditions = 68 Deg F (A)
29.92 "Hg (B)

Equations
CSA = ID^2 / 183.3465
Vms = (17.71)(Y)(Vm)(((H / 13.6) + Pb) / (Tm + 460))
Vws = Wc / 21.2
Bws = (100)(Vws) / (Vms + Vws)
MWd = (CO2)(0.44) + (O2)(0.32) + (100 - (CO2 + O2))(.28)
MWw = (Bws)(0.18) + ((MWd)(100 - Bws) / 100)
Pa = Pb + (Ps1 / 13.6)
Vsa = (((Ts + 460) / (((Ps / 13.6) + Pb)(MWw)))^0.5)(Cp)(dP)(85.49)
Vss = (((Vsa)(((Ps / 13.6) + Pb) / (Ts + 460)))(17.71 / 2)
ACFM = (Vsa)(CSA)(60 sec/min)
SCFM = (Vss)(CSA)(60 sec/min)
DSCFM = ((100 - Bws)/ 100)(SCFM)

Minute	Flow Time	Delta P ("H2O)	Stack Temp (Deg F)	Square Root Delta P	Gas Meter Temps (deg F) In	Gas Meter Temps (deg F) Out	Stack Velocities (feet/sec) Ave. Actual (Vsa)	Stack Velocities (feet/sec) Std. Actual (Vss)	Stack Flow Rate Ave. Actual (acfm)	Stack Flow Rate Std. Ave. (scfm)
0	1709	1.6	174	1.265	90	91	77.84	65.28	22169.10	18591.82
1	1710	1.6	174	1.265	95	90	77.84	65.28	22169.10	18591.82
2	1711	1.6	175	1.265	98	91	77.91	65.23	22186.58	18577.17
3	1712	1.6	175	1.265	102	91	77.91	65.23	22186.58	18577.17
4	1713	1.6	176	1.265	108	92	77.97	65.18	22204.04	18562.56
5	1714	1.6	176	1.265	110	93	77.97	65.18	22204.04	18562.56
6	1715	1.6	177	1.265			78.03	65.13	22221.49	18547.98
7	1716	1.6	177	1.265			78.03	65.13	22221.49	18547.98
8	1717	1.6	178	1.265			78.09	65.08	22238.93	18533.44
9	1718	1.6	178	1.265			78.09	65.08	22238.93	18533.44
10	1719	1.6	178	1.265			78.09	65.08	22238.93	18533.44
11	1720	1.6	179	1.265			78.15	65.03	22256.35	18518.94
12	1721	1.6	180	1.265			78.21	64.98	22273.76	18504.46
13	1722	1.6	181	1.265			78.27	64.93	22291.15	18490.02
14	1723	1.6	182	1.265			78.33	64.87	22308.53	18475.62
15	1724	1.6	183	1.265			78.39	64.82	22325.90	18461.24
16	1725	1.6	184	1.265			78.46	64.77	22343.25	18446.90
17	1726	1.6	185	1.265			78.52	64.72	22360.59	18432.60
18	1727	1.6	186	1.265			78.58	64.67	22377.92	18418.33
19	1728	1.6	186	1.265			78.58	64.67	22377.92	18418.33
20	1729	1.6	187	1.265			78.64	64.62	22395.23	18404.09
21	1730	1.6	187	1.265			78.64	64.62	22395.23	18404.09
22										
23										
24										
Averages:		1.600	180 [Ts]	1.265 [dP]		95.9 [Tm]	78.21	64.98	22272.05	18506.09

Run 3



y = -0.2114x^2 - 5.2495x + 18593
F(x) = -(0.2114/3)x^3 - (5.2495/2)x^2 + 18593x +c

x	F(x)		
0	= -(0.2114/3)*0^3 - (5.2495/2)*0^2 + 18593*0 + c	=	0.00
21	= -(0.2114/3)*21^3 - (5.2495/2)*21^2 + 18593*21 + c	=	388,642.89
Area	= F(21) - F(0)	=	**388,642.89** V (scf)*

*Calculated in accordance with Subpart O by integrating area under curve plotted using volumetric flowrate vs time.

CatOx Outlet Diluent Concentrations of O_2 & CO_2 during Sterilization

Customer Name: B Braun
Location: Allentown,PA
Source: CatOx Outlet

Run No.	1	2	3
Date	12/15/20	12/15/20	12/15/20
Time	0836-0858	1310-1332	1709-1730

Outlet- Oxygen (O_2)

	1	2	3	Average
Average Zero Response (%) (F)	-0.020	0.050	0.035	
Average Upscale Response (%) (G)	11.945	12.000	12.015	
Bias Gas Value (%) (H)	11.92	11.92	11.92	
Run Average, dry, uncorrected (%) (I)	20.36	20.43	20.46	
Run Average, dry, corrected (%) (J)	**20.31**	**20.33**	**20.32**	**20.32**

Outlet- Carbon Dioxide (CO_2)

	1	2	3	Average
Average Zero Response (%) (F)	0.225	0.230	0.255	
Average Upscale Response (%) (G)	9.385	9.325	9.395	
Bias Gas Value (%) (H)	9.229	9.229	9.229	
Run Average, dry, uncorrected (%) (I)	0.71	0.62	0.63	
Run Average, dry, corrected (%) (J)	**0.49**	**0.39**	**0.38**	**0.42**

Equations:

(J)=(I-F)(H)/(G-F)

Definitions:

(F) = Analyzer response to zero gas
(G) = Analyzer response to span gas
(H) = Calibration gas concentration
(I) = Analyzer response to stack gas, measured dry.

AERATION ROOM

EtO Emissions during Aeration Room Test

Customer Name: B Braun
Location: Allentown, PA
Source: Catalytic Oxidizer Outlet

	Run No.	1	2	3	Averages
	Date	12/15/20	12/15/20	12/15/20	
	Time	1042-1142	1155-1255	1535-1635	
Stack Moisture (%) (A)		0.56	1.49	0.77	0.94

Ethylene Oxide (EtO)

	1	2	3	Averages	Emission Limit
Run Average, wet (ppmv) (B)	0.71	0.65	0.73		
Run Average, dry (ppmv) (C)	**0.71307**	**0.65774**	**0.73126**	**0.70069**	**1.0**

Equations:

(C) = (B) / ((100 - A) / 100)

Definitions:

(A) = In-stack moisture as measured by U.S. EPA Method 4.

(B) = Analyzer response to stack gas; EtO is measured wet.

STACK MOISTURE CALCULATOR DURING AERATION

Run Times:

	Run 1		Run 2		Run 3	
Run Times	1042-1142		1155-1255		1535-1635	
	IN	OUT	IN	OUT	IN	OUT
Meter Temperatures in Degrees F						
	80	78	92	91	86	87
	82	79	96	90	86	86
	84	79	99	90	89	85
	88	80	101	90	92	85
	90	80	102	91	94	86
	93	81	104	92	96	86
	95	82	105	92	98	87
	97	84	106	93	100	88
	98	85	106	94	101	89
	99	85	107	94	102	90
	100	87	107	94	103	90
	102	88	108	95	104	91
Average Meter Temps.:		87.3		97.5		91.7
		(A)		(A)		(A)

Customer:	B Braun
Location:	Allentown, PA
Source:	Catalytic Oxidizer Outlet
Date:	12/15/20

Run 1

Impinger Weights		
Final Wt	Initial Wt	Gain
773.6	771.1	2.5
690.6	691.2	-0.6
657.3	658.1	-0.8
966.0	963.1	2.9
Water Caught (gms)		4.0

Run 2

Impinger Weights		
Final Wt	Initial Wt	Gain
720.7	716.3	4.4
720.0	719.2	0.8
639.8	639.1	0.7
965.9	961.1	4.8
Water Caught (gms)		10.7

Run 3

Impinger Weights		
Final Wt	Initial Wt	Gain
722.4	720.7	1.7
719.9	720.0	-0.1
639.8	639.8	0.0
969.8	965.9	3.9
Water Caught (gms)		5.5

INPUT DATA	Run 1	Run 2	Run 3
Beginning Meter Setting (cubic feet) (A):	62.770	96.715	155.275
Ending Meter Setting (cubic feet) (A1):	96.540	130.925	189.100
Meter Volume, (cubic feet) (C):	33.770	34.210	33.825
Water Caught (grams) (D):	4.0	10.7	5.5
Barometric Pressure ("Hg) (B):	30.31	30.31	30.35
Meter Correction Factor (E):	1.014	1.014	1.014
Average Delta H ("H2O) (F):	1.00	1.00	1.00

OUTPUT DATA	Run 1	Run 2	Run 3
Metered Volume (Std.cu.ft.) (G):	33.545	33.365	33.377
Moisture Volume (cubic feet) (H):	0.19	0.50	0.26
Percent Moisture (J):	**0.56**	**1.49**	**0.77**

Calculations

G = ((F /13.6)+ B)/(A +460 deg R)*((L +460)/M)* C * E
H = D / 21.2 grams H2O/cubic foot of saturated air at 68 deg F and 29.92" Hg
J = 100 * H / (H + G)

Standard Conditions = 68 deg F (L)
29.92 "Hg (M)

APPENDIX C

RUN DATA

STERILIZATION CHAMBER

PACE Environmental
Minute Average

Date	Time	O_2 (%)	CO_2 (%)	THC (ppm)
12/15/20	8:36:26	20.57	0.56	0.62
12/15/20	8:37:26	20.43	0.59	0.59
12/15/20	8:38:27	20.30	0.66	0.64
12/15/20	8:39:26	20.25	0.70	0.65
12/15/20	8:40:27	20.24	0.71	0.71
12/15/20	8:41:26	20.26	0.70	0.73
12/15/20	8:42:27	20.25	0.73	0.73
12/15/20	8:43:26	20.26	0.74	0.72
12/15/20	8:44:26	20.25	0.76	0.72
12/15/20	8:45:27	20.26	0.75	0.76
12/15/20	8:46:26	20.29	0.74	0.78
12/15/20	8:47:26	20.32	0.74	0.75
12/15/20	8:48:26	20.34	0.74	0.79
12/15/20	8:49:27	20.35	0.74	0.74
12/15/20	8:50:26	20.39	0.74	0.76
12/15/20	8:51:26	20.41	0.73	0.73
12/15/20	8:52:26	20.43	0.73	0.73
12/15/20	8:53:27	20.44	0.73	0.76
12/15/20	8:54:27	20.48	0.73	0.72
12/15/20	8:55:26	20.49	0.73	0.78
12/15/20	8:56:27	20.49	0.73	0.79
12/15/20	8:57:27	20.49	0.73	0.79
Averages		**20.36**	**0.71**	**0.73**
Minimum		**20.24**	**0.56**	**0.59**
Maximum		**20.57**	**0.76**	**0.79**

PACE Environmental
Minute Average

Date	Time	O_2 (%)	CO_2 (%)	THC (ppm)
12/15/20	13:10:27	20.65	0.52	0.63
12/15/20	13:11:27	20.60	0.53	0.64
12/15/20	13:12:27	20.44	0.55	0.70
12/15/20	13:13:27	20.35	0.61	0.72
12/15/20	13:14:27	20.33	0.64	0.74
12/15/20	13:15:27	20.31	0.65	0.74
12/15/20	13:16:27	20.30	0.67	0.77
12/15/20	13:17:27	20.36	0.64	0.79
12/15/20	13:18:27	20.35	0.65	0.79
12/15/20	13:19:27	20.34	0.67	0.80
12/15/20	13:20:27	20.37	0.64	0.81
12/15/20	13:21:27	20.37	0.64	0.82
12/15/20	13:22:27	20.36	0.65	0.83
12/15/20	13:23:26	20.40	0.64	0.83
12/15/20	13:24:27	20.41	0.63	0.84
12/15/20	13:25:27	20.45	0.61	0.84
12/15/20	13:26:27	20.45	0.64	0.83
12/15/20	13:27:27	20.48	0.61	0.84
12/15/20	13:28:27	20.50	0.60	0.85
12/15/20	13:29:27	20.53	0.61	0.85
12/15/20	13:30:27	20.54	0.61	0.85
12/15/20	13:31:27	20.56	0.60	0.84
Averages		**20.43**	**0.62**	**0.79**
Minimum		**20.30**	**0.52**	**0.63**
Maximum		**20.65**	**0.67**	**0.85**

PACE Environmental
Minute Average

Date	Time	O_2 (%)	CO_2 (%)	THC (ppm)
12/15/20	17:09:27	20.69	0.49	0.65
12/15/20	17:10:27	20.60	0.51	0.64
12/15/20	17:11:27	20.46	0.54	0.68
12/15/20	17:12:27	20.38	0.60	0.71
12/15/20	17:13:27	20.34	0.63	0.72
12/15/20	17:14:27	20.34	0.65	0.73
12/15/20	17:15:27	20.32	0.66	0.73
12/15/20	17:16:27	20.31	0.69	0.73
12/15/20	17:17:27	20.35	0.67	0.78
12/15/20	17:18:27	20.38	0.65	0.78
12/15/20	17:19:27	20.38	0.66	0.79
12/15/20	17:20:27	20.41	0.65	0.81
12/15/20	17:21:27	20.44	0.65	0.80
12/15/20	17:22:27	20.45	0.65	0.80
12/15/20	17:23:27	20.48	0.65	0.83
12/15/20	17:24:27	20.51	0.65	0.82
12/15/20	17:25:27	20.53	0.64	0.83
12/15/20	17:26:27	20.56	0.63	0.83
12/15/20	17:27:27	20.56	0.66	0.82
12/15/20	17:28:27	20.57	0.66	0.82
12/15/20	17:29:27	20.60	0.63	0.84
Averages		**20.46**	**0.63**	**0.77**
Minimum		**20.31**	**0.49**	**0.64**
Maximum		**20.69**	**0.69**	**0.84**

<u>AERATION ROOM</u>

PACE Environmental
Minute Average

Date	Time	EtO (ppm)
12/15/20	10:42:26	0.73
12/15/20	10:43:27	0.72
12/15/20	10:44:27	0.75
12/15/20	10:45:27	0.76
12/15/20	10:46:27	0.71
12/15/20	10:47:26	0.71
12/15/20	10:48:27	0.72
12/15/20	10:49:26	0.72
12/15/20	10:50:27	0.72
12/15/20	10:51:26	0.72
12/15/20	10:52:26	0.73
12/15/20	10:53:27	0.73
12/15/20	10:54:26	0.73
12/15/20	10:55:27	0.72
12/15/20	10:56:26	0.72
12/15/20	10:57:27	0.72
12/15/20	10:58:26	0.70
12/15/20	10:59:26	0.69
12/15/20	11:00:27	0.69
12/15/20	11:01:26	0.69
12/15/20	11:02:26	0.75
12/15/20	11:03:26	0.74
12/15/20	11:04:27	0.68
12/15/20	11:05:26	0.68
12/15/20	11:06:26	0.74
12/15/20	11:07:26	0.73
12/15/20	11:08:26	0.73
12/15/20	11:09:27	0.68
12/15/20	11:10:26	0.67
12/15/20	11:11:27	0.70
12/15/20	11:12:27	0.71
12/15/20	11:13:26	0.70
12/15/20	11:14:26	0.70
12/15/20	11:15:27	0.70
12/15/20	11:16:27	0.70
12/15/20	11:17:26	0.70
12/15/20	11:18:27	0.70
12/15/20	11:19:27	0.71
12/15/20	11:20:26	0.70
12/15/20	11:21:26	0.70
12/15/20	11:22:26	0.70
12/15/20	11:23:27	0.67

Aeration Room- EtO Run 001

Date	Time	EtO (ppm)
12/15/20	11:24:26	0.65
12/15/20	11:25:27	0.67
12/15/20	11:26:27	0.68
12/15/20	11:27:26	0.68
12/15/20	11:28:27	0.68
12/15/20	11:29:26	0.69
12/15/20	11:30:26	0.69
12/15/20	11:31:27	0.70
12/15/20	11:32:26	0.70
12/15/20	11:33:27	0.71
12/15/20	11:34:26	0.71
12/15/20	11:35:27	0.71
12/15/20	11:36:26	0.72
12/15/20	11:37:26	0.72
12/15/20	11:38:27	0.75
12/15/20	11:39:26	0.76
12/15/20	11:40:27	0.71
12/15/20	11:41:26	0.72
Averages		**0.71**
Minimum		**0.65**
Maximum		**0.76**

PACE Environmental
Minute Average

Date	Time	EtO (ppm)
12/15/20	11:55:27	0.69
12/15/20	11:56:27	0.69
12/15/20	11:57:27	0.69
12/15/20	11:58:26	0.68
12/15/20	11:59:26	0.68
12/15/20	12:00:27	0.68
12/15/20	12:01:27	0.68
12/15/20	12:02:26	0.67
12/15/20	12:03:27	0.67
12/15/20	12:04:27	0.67
12/15/20	12:05:26	0.67
12/15/20	12:06:26	0.67
12/15/20	12:07:26	0.67
12/15/20	12:08:27	0.67
12/15/20	12:09:26	0.66
12/15/20	12:10:27	0.67
12/15/20	12:11:27	0.67
12/15/20	12:12:26	0.66
12/15/20	12:13:27	0.66
12/15/20	12:14:26	0.66
12/15/20	12:15:26	0.65
12/15/20	12:16:27	0.62
12/15/20	12:17:27	0.62
12/15/20	12:18:27	0.62
12/15/20	12:19:26	0.62
12/15/20	12:20:27	0.67
12/15/20	12:21:26	0.68
12/15/20	12:22:26	0.65
12/15/20	12:23:27	0.61
12/15/20	12:24:26	0.66
12/15/20	12:25:27	0.67
12/15/20	12:26:26	0.67
12/15/20	12:27:27	0.61
12/15/20	12:28:27	0.60
12/15/20	12:29:26	0.65
12/15/20	12:30:27	0.66
12/15/20	12:31:26	0.64
12/15/20	12:32:27	0.64
12/15/20	12:33:26	0.63
12/15/20	12:34:27	0.63
12/15/20	12:35:26	0.63
12/15/20	12:36:26	0.63

Aeration Room- EtO Run 002

Date	Time	EtO (ppm)
12/15/20	12:37:26	0.63
12/15/20	12:38:26	0.63
12/15/20	12:39:27	0.64
12/15/20	12:40:27	0.64
12/15/20	12:41:27	0.63
12/15/20	12:42:27	0.63
12/15/20	12:43:26	0.63
12/15/20	12:44:26	0.63
12/15/20	12:45:27	0.63
12/15/20	12:46:27	0.62
12/15/20	12:47:27	0.62
12/15/20	12:48:27	0.63
12/15/20	12:49:27	0.63
12/15/20	12:50:27	0.63
12/15/20	12:51:27	0.66
12/15/20	12:52:27	0.66
12/15/20	12:53:27	0.60
12/15/20	12:54:26	0.61

Averages	**0.65**
Minimum	**0.60**
Maximum	**0.69**

PACE Environmental
Minute Average

Date	Time	EtO (ppm)
12/15/20	15:35:27	0.75
12/15/20	15:36:27	0.77
12/15/20	15:37:27	0.72
12/15/20	15:38:27	0.71
12/15/20	15:39:27	0.77
12/15/20	15:40:27	0.76
12/15/20	15:41:27	0.76
12/15/20	15:42:27	0.73
12/15/20	15:43:27	0.71
12/15/20	15:44:27	0.71
12/15/20	15:45:27	0.71
12/15/20	15:46:27	0.75
12/15/20	15:47:27	0.76
12/15/20	15:48:27	0.76
12/15/20	15:49:27	0.71
12/15/20	15:50:27	0.71
12/15/20	15:51:27	0.73
12/15/20	15:52:27	0.78
12/15/20	15:53:27	0.76
12/15/20	15:54:27	0.71
12/15/20	15:55:27	0.71
12/15/20	15:56:27	0.71
12/15/20	16:10:36	0.73
12/15/20	16:11:50	0.73
12/15/20	16:11:50	0.73
12/15/20	16:11:50	0.72
12/15/20	16:11:50	0.73
12/15/20	16:11:50	0.72
12/15/20	16:11:50	0.72
12/15/20	16:11:50	0.72
12/15/20	16:11:50	0.72
12/15/20	16:11:50	0.72
12/15/20	16:11:50	0.73
12/15/20	16:11:50	0.72
12/15/20	16:11:50	0.73
12/15/20	16:11:50	0.72
12/15/20	16:11:51	0.72
12/15/20	16:12:27	0.72
12/15/20	16:13:27	0.72
12/15/20	16:14:27	0.72
12/15/20	16:15:27	0.73

Aeration Room- EtO Run 003

Date	Time	EtO (ppm)
12/15/20	16:16:27	0.73
12/15/20	16:17:27	0.73
12/15/20	16:18:27	0.72
12/15/20	16:19:27	0.69
12/15/20	16:20:27	0.69
12/15/20	16:21:27	0.69
12/15/20	16:22:27	0.69
12/15/20	16:23:27	0.74
12/15/20	16:24:27	0.75
12/15/20	16:25:27	0.74
12/15/20	16:26:27	0.73
12/15/20	16:27:27	0.68
12/15/20	16:28:27	0.69
12/15/20	16:29:27	0.72
12/15/20	16:30:27	0.72
12/15/20	16:31:27	0.72
12/15/20	16:32:27	0.72
12/15/20	16:33:27	0.72
12/15/20	16:34:27	0.72
	Averages	**0.73**
	Minimum	**0.68**
	Maximum	**0.78**

APPENDIX D

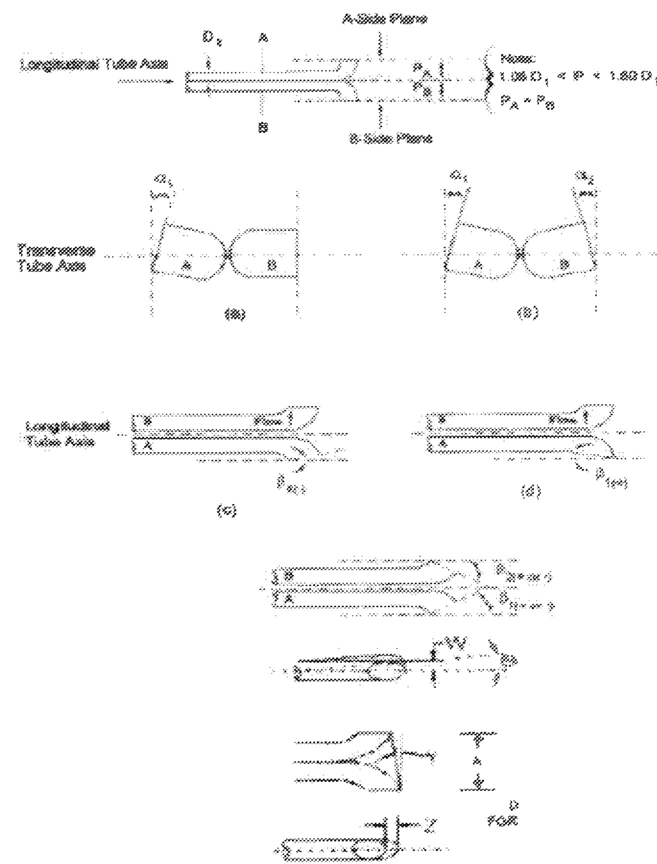
CALIBRATION DATA

Equipment Calibration Documentation

Pitot Tube Inspection Form

Date: 05/06/20
Checked By: CW
Pitot ID: 6-1

Parameter	Allowable Range	Value	Passed
Ports Damaged	No	No	PASS
D_t	$0.188" \leq D_T \leq 0.375"$	0.25	PASS
P_A	$P_A = P_B$	0.35	PASS
P_B		0.35	
P	$1.05D_T \leq P \leq 1.50D_T$	$0.263 \leq 0.350 \leq 0.375$	PASS
α_1	± 10°	0	PASS
α_2	± 10°	0	PASS
β_1	± 5°	2.1	PASS
β_2	± 5°	3.5	PASS
A	N/A	0.7	N/A
γ	N/A	1.5	N/A
θ	N/A	0.4	N/A
Z = A tan γ	± 0.125"	0.018	PASS
W = A tan θ	± 0.031"	0.005	PASS



This pitot meets all applicable specifications, criteria, and design features and has been assigned a pitot tube factor of 0.84.

METHOD 5 DRY GAS METER CALIBRATION USING CRITICAL ORIFICES

PACE ENVIRONMENTAL

1) Select three critical orifices to calibrate the dry gas meter which bracket the expected operating range.
2) *Record barometric pressure before and after calibration procedure.*
3) Run at tested vacuum (from Orifice Calibration Report), for a period of time necessary to achieve a minimum total volume of 5 cubic feet.
4) Record data and information in the GREEN cells, YELLOW cells are calculated.

DATE: 12/10/2020 METER SERIAL #:

METER PART #: MB04 CRITICAL ORIFICE SET SERIAL #: 1764

	INITIAL	FINAL	AVG (P_{bar})
BAROMETRIC PRESSURE (in Hg):	30.12	30.13	30.125

ORIFICE #	RUN #	K' FACTOR (AVG)	TESTED VACUUM (in Hg)	DGM READINGS (FT³) INITIAL	FINAL	NET (V_m)	TEMPERATURES °F AMBIENT	DGM INLET INITIAL	DGM INLET FINAL	DGM OUTLET INITIAL	DGM OUTLET FINAL	DGM AVG	ELAPSED TIME (MIN) θ	DGM ΔH (in H_2O)	(1) V_m (STD)	(2) V_{cr} (STD)	(3) Y	Y % Diff to Average Y	Y % Diff with other orifices	$\Delta H_@$
32	1	0.8316	16	950.065	955.945	5.880	63	68	72	68	68	69	5.50	3.7	5.9636	6.0267	1.011			1.76
	2	0.8316	16	955.945	962.640	6.695	63	72	74	68	68	70.5	6.25	3.7	6.7709	6.8486	1.011			1.75
	3	0.8316	16	962.640	968.525	5.885	63	74	77	68	68	71.75	5.50	3.7	5.9378	6.0267	1.015			1.75
																AVG =	1.012		-0.31	
26	1	0.6825	16	968.525	973.835	5.310	63	72	77	69	69	71.75	6.00	2.5	5.3420	5.3958	1.010			1.75
	2	0.6825	16	973.835	979.140	5.305	63	77	81	69	70	74.25	6.00	2.5	5.3120	5.3958	1.016			1.74
	3	0.6825	16	979.140	984.440	5.30	63	81	83	70	71	76.25	6.00	2.5	5.2872	5.3958	1.021			1.73
																AVG =	1.015	0.17	0.31	
20	1	0.5358	16	999.875	1,005.480	5.605	63	84	86	74	74	79.5	8.00	1.5	5.5443	5.6480	1.019			1.67
	2	0.5358	16	1,005.480	1,012.670	7.190	63	86	87	74	76	80.75	10.25	1.5	7.0957	7.2365	1.020			1.67
	3	0.5358	16	1,012.670	1,021.465	8.795	63	87	89	76	77	82.25	12.50	1.5	8.6556	8.8251	1.020			1.67
																AVG =	1.019	0.55	0.39	
17	1	0.4499	16	984.440	989.580	5.140	63	83	82	71	72	77	8.75	1.1	5.1030	5.1872	1.016			1.75
	2	0.4499	16	989.580	994.730	5.150	63	82	83	72	73	77.5	8.75	1.1	5.1082	5.1872	1.015			1.75
	3	0.4499	16	994.730	999.875	5.145	63	83	84	73	74	78.5	8.75	1.1	5.0938	5.1872	1.018			1.74
																AVG =	1.017	0.30	1.19	
12	1	0.3195	16	1,021.465	1,026.70	5.235	63	84	83	74	77	79.5	12.50	0.56	5.1665	5.2624	1.019			1.75
	2	0.3195	16	1,026.80	1,032.050	5.250	63	83	83	77	77	80	12.50	0.56	5.1765	5.2624	1.017			1.75
	3	0.3195	16	1,032.050	1,037.50	5.450	63	83	83	77	77	80	12.50	0.56	5.3737	5.2624	0.979			1.75
																AVG =	1.005	-0.88	-1.17	

USING THE CRITICAL ORIFICES AS CALIBRATION STANDARDS:
The following equations are used to calculate the standard volumes of air passed through the DGM, V_m (std), and the critical orifice, V_{cr} (std), and the DGM calibration factor, Y. These equations are automatically calculated in the spreadsheet above.

AVERAGE DRY GAS METER CALIBRATION FACTOR, Y = **1.014**

-0.14

AVERAGE $\Delta H_@$ = **1.73**

(1) $Vm_{(std)} = K_1 * Vm * \frac{Pbar + (\Delta H / 13.6)}{Tm}$ = Net volume of gas sample passed through DGM, corrected to standard conditions

K_1 = 17.64 °R/in. Hg (English), 0.3858 °K/mm Hg (Metric)

T_m = Absolute DGM avg. temperature (°R - English, °K - Metric)

$$\Delta H_@ = \left(\frac{0.75\,\theta}{V_{cr}(std)}\right)^2 \Delta H \left(\frac{V_m(std)}{V_m}\right)$$

(2) $Vcr_{(std)} = K' * \frac{Pbar * \Theta}{\sqrt{Tamb}}$ = Volume of gas sample passed through the critical orifice, corrected to standard conditions

T_{amb} = Absolute ambient temperature (°R - English, °K - Metric)

K' = Average K' factor from Critical Orifice Calibration

(3) $Y = \frac{Vcr_{(std)}}{Vm_{(std)}}$ = DGM calibration factor

METHOD 5 DRY GAS METER CALIBRATION USING CRITICAL ORIFICES

1) Select three critical orifices to calibrate the dry gas meter which bracket the expected operating range.
2) Record barometric pressure before and after calibration procedure.
3) Run at tested vacuum (from Orifice Calibration Report), for a period of time necessary to achieve a minimum total volume of 5 cubic feet.
4) Record data and information in the GREEN cells, YELLOW cells are calculated.

DATE: 2/9/2021 METER SERIAL #:

METER PART #: MB04 CRITICAL ORIFICE SET SERIAL #: CO-1764s

	INITIAL	FINAL	AVG (P_{bar})
BAROMETRIC PRESSURE (in Hg):	30.02	30	30.01

ORIFICE #	RUN #	K' FACTOR (AVG)	TESTED VACUUM (in Hg)	DGM READINGS (FT³) INITIAL	FINAL	NET (V_m)	TEMPERATURES °F AMBIENT	DGM INLET INITIAL	DGM INLET FINAL	DGM OUTLET INITIAL	DGM OUTLET FINAL	DGM AVG	ELAPSED TIME (MIN) θ	DGM ΔH (in H_2O)	(1) V_m (STD)	(2) V_{cr} (STD)	(3) Y	Y % Diff to Average Y	Y % Diff with other orifices	$\Delta H_@$
32	1	0.8316	15	289.005	294.015	5.010	65	68	69	68	68	68.25	4.75	3.7	5.0692	5.1751	1.021			1.77
	2	0.8316	15	294.015	299.015	5.0	65	69	71	68	68	69	4.75	3.7	5.0519	5.1751	1.024			1.77
	3	0.8316	15	299.015	304.015	5.0	65	17	74	69	69	57.25	4.75	3.7	5.1667	5.1751	1.002			1.81
																AVG =	1.016	-0.51	-0.50	
20	1	0.5358	16	304.015	309.015	5.0	63	74	77	69	70	72.5	7.25	1.5	4.9918	5.0990	1.021			1.70
	2	0.5358	16	309.015	314.015	5.0	63	77	80	70	71	74.5	7.25	1.5	4.9732	5.0990	1.025			1.70
	3	0.5358	16	314.015	319.110	5.095	63	80	80	71	72	75.75	7.30	1.5	5.0558	5.1342	1.015			1.69
																AVG =	1.021	-0.01	0.50	
12	1	0.3195	16	319.110	324.310	5.20	63	80	82	72	72	76.5	12.50	0.56	5.1410	5.2423	1.020			1.77
	2	0.3195	16	324.310	329.310	5.0	61	82	86	72	77	79.25	12.00	0.56	4.9180	5.0423	1.025			1.75
	3	0.3195	16	329.310	334.310	5.0	59	86	88	77	79	82.5	12.00	0.56	4.8885	5.0520	1.033			1.74
																AVG =	1.026	0.52	1.03	

USING THE CRITICAL ORIFICES AS CALIBRATION STANDARDS:
The following equations are used to calculate the standard volumes of air passed through the DGM, V_m (std), and the critical orifice, V_{cr} (std), and the DGM calibration factor, Y. These equations are automatically calculated in the spreadsheet above.

AVERAGE DRY GAS METER CALIBRATION FACTOR, Y = **1.021**

AVERAGE $\Delta H_@$ = **1.75**

(1) $$Vm_{(std)} = K_1 * Vm * \frac{Pbar + (\Delta H / 13.6)}{Tm}$$ = Net volume of gas sample passed through DGM, corrected to standard conditions

K_1 = 17.64 °R/in. Hg (English), 0.3858 °K/mm Hg (Metric)

T_m = Absolute DGM avg. temperature (°R - English, °K - Metric)

$$\Delta H_@ = \left(\frac{0.75\,\theta}{V_{cr}(std)}\right)^2 \Delta H \left(\frac{V_m(std)}{V_m}\right)$$

(2) $$Vcr_{(std)} = K' * \frac{Pbar * \Theta}{\sqrt{Tamb}}$$ = Volume of gas sample passed through the critical orifice, corrected to standard conditions

T_{amb} = Absolute ambient temperature (°R - English, °K - Metric)

K' = Average K' factor from Critical Orifice Calibration

(3) $$Y = \frac{Vcr_{(std)}}{Vm_{(std)}}$$ = DGM calibration factor

Thermocouple Calibration Certification

Annual Calibration

Annual Calibration Date: 02/02/20

NIST Reference Thermometer ID No. Omega 1

Calibrated On: 02/02/20

Calibration Due: 02/02/21

Thermocouple ID No.	Ice Water Bath			Ambient			Boiling Water		
	TC readout (°F)	Reference (°F)	Difference (%)	TC readout (°F)	Reference (°F)	Difference (%)	TC readout (°F)	Reference (°F)	Difference (%)
Probe 6-1	28	28.1	-0.02	64	64.5	-0.10	212	212.7	-0.10

Thermocouple temperature readouts are considered acceptable if the thermocouple and reference thermometer absolute temperatures agree within ± 1.5% (Section 10.3 of Method 2)

Post-Test Calibration

Post-Test Calibration Date: 12/16/20

Calibration Completed By: BG

	Thermocouple ID No.:	Probe 6-1					M8-04 Gas Meter (In)	M8-04 Gas Meter (Out)	Gooseneck 2
Ambient Temperature Check	TC Readout (°F):	60					60	60	60
	Reference (°F):	60					60	60	60
	Difference (°F):	0.0					0.0	0.0	0.0

Thermocouple temperature readouts are considered acceptable if the thermocouple and reference thermometer temperatures agree within ± 2°F (alternate calibration procedure of Section 10.5 of Method 5)

Analyzer Calibration Documentation

FM0006 Compliance Test Field Data Sheet

Company	BBRAUN
Location	BETHLEHEM, PA
Source	ETO CONTROL
Date	12/15/20
Time	

DIRECT CALIBRATIONS

Analyzer Type	Zero	Gas 1 Value 24.82 O2	Gas 2 Value 18.59 CO2	Gas 3 Value 11.92 O2	Gas 4 Value 9.229 CO2	Gas 5 Value	Gas 6 Value	Gas 7 Value	Gas 8 Value	Gas 9 Value	Gas 10 Value	Gas 11 Value	Gas 12 Value
O2	-0.07	24.06		12.00									
CO2	0.04		18.76		9.28								
Time	723	726	726	729	729								

Initial Bias

Analyzer Type	Zero	Bias 1 Value 11.92 O2	Bias 2 Value 9.229 CO2	Bias 3 Value 8.952 ETO	Bias 4 Value 5.298 ETO	Bias 5 Value 3.140 ETO	Bias 6 Value	Bias 7 Value	Bias 8 Value	Bias 9 Value	Bias 10 Value	Bias 11 Value	Bias 12 Value
O2	-0.01	11.95											
CO2	0.08		9.24										
THC ETO	0.01			8.87	5.23	3.13							
Time	738	740	740	822	819	815							

RUN	1	STERILIZATION						
Start: 836				Stop: ~~858~~ 0858				
Bias								
Analyzer Type	Zero	Bias 1 Value 11.92 O2	Bias 2 Value 9.229 CO2	Bias 3 Value 3.140 ETO	Bias 4 Value	Bias 5 Value	Bias 6 Value	
O2	-0.03	11.94						
CO2	0.37		9.53					
THC ETO	0.00			3.09				HL 270 270
								HL 270 270
								HL 270 270
								HL 270 270
								HL 270 270
								HL
								HL
								HL
Time	905	908	908	902				HL

Channel Inputs

A ______
B ______
C ______
D ______
E ______
F ______
G ______
H ______
I ______
J ______
K ______
L ______
M ______

STRAT 839 - 852

RUN 1 AERATION										
Start: 1042				Stop: 1142						
Bias										
Analyzer Type	Zero	Bias 1 Value 11.92 O2	Bias 2 Value 9.229 CO2	Bias 3 Value 3,140 ETO	Bias 4 Value	Bias 5 Value	Bias 6 Value			
O2	0.03	12.01								
CO2	0.36		9.45							
THC ETO	0.00			3.17				HL	270	270
								HL	270	270
								HL	270	270
								HL	270	270
								HL	270	270
								HL		
								HL		
Time	1150	1147	1147	1149				HL		

RUN 2 AERATION										
Start: 1155				Stop: 1255						
Bias										
Analyzer Type	Zero	Bias 1 Value 11.92 O2	Bias 2 Value 9.229 CO2	Bias 3 Value 3.140 ETO	Bias 4 Value	Bias 5 Value	Bias 6 Value			
O2	0.04	11.98								
CO2	0.25		9.34							
THC ETO	0.02			3.17				HL	270	270
								HL	270	270
								HL	270	270
								HL	270	270
								HL	270	270
								HL		
								HL		
Time	1300	1302	1302	1257				HL		

RUN 2 STERILIZATION										
Start: 1310				Stop: ~~1331~~ 1332						
Bias										
Analyzer Type	Zero	Bias 1 Value 11.92 O2	Bias 2 Value 9.229 CO2	Bias 3 Value 3,140 ETO	Bias 4 Value	Bias 5 Value	Bias 6 Value			
O2	0.06	12.02								
CO2	0.21		9.31							
THC ETO	0.02			3.12				HL	270	270
								HL	270	270
								HL	270	270
								HL	270	270
								HL	270	270
								HL		
								HL		
Time	1353	1355	1355	1351				HL		

RUN 3 AERATION										
Start: 1535				Stop: 1635						
Bias										
Analyzer Type	Zero	Bias 1 Value 11.92 O2	Bias 2 Value 9.22 CO2	Bias 3 Value 3.40 ETO	Bias 4 Value	Bias 5 Value	Bias 6 Value			
O2	0.04	12.01								
CO2	0.22		9.36							
THC ETO	0.00			3.11				HL	270	270
								HL	270	270
								HL	270	270
								HL	270	270
								HL	270	270
								HL	270	270
								HL		
Time	1642	1645	1645	1640				HL		

RUN 3 STERILIZATION										
Start: ~~1215~~ 1709				Stop: 1730						
Bias										
Analyzer Type	Zero	Bias 1 Value 11.92 O2	Bias 2 Value 9.22 CO2	Bias 3 Value 3.41 ETO	Bias 4 Value	Bias 5 Value	Bias 6 Value			
O2	0.03	12.02								
CO2	0.29		9.43							
THC ETO	0.00			3.09				HL	270	270
								HL	270	270
								HL	270	270
								HL	270	270
								HL	270	270
								HL	270	270
								HL		
Time	1734	1732	1732	1732				HL		

RUN								
Start:				Stop:				
Bias								
Analyzer Type	Zero	Bias 1 Value	Bias 2 Value	Bias 3 Value	Bias 4 Value	Bias 5 Value	Bias 6 Value	
								HL
								HL
								HL
								HL
								HL
								HL
								HL
Time								HL

QA/QC Bias/Drift Calculator

Oxygen

Calibration Gas Standard Concentrations (%) (C_v)		
Zero	Mid	High/Span (CS)
0.00	11.92	24.02

Analyzer Calibration Error (ACE ≤ 2% of range)			
Actual Analyzer Response (C_{Dir}):	-0.07	12.00	24.06
Analyzer Cal Error (%)	-0.29	0.33	0.17

Initial System Bias (SB ≤ 5% of range)		
	Zero	Bias Gas
Cal Gas Standard Concentration:	0.00	11.92
Actual Analyzer Response (C_s):	-0.01	11.95
Initial System Bias (%)	0.25	-0.21
Sterilization Post Run 1 Drift (D ≤ 3% of range)		
Actual Analyzer Response:	-0.03	11.94
System Bias (%)	0.17	-0.25
Drift (%):	0.08	0.04
Aeration Post Run 1 Drift (D ≤ 3% of range)		
Actual Analyzer Response:	0.03	12.01
System Bias (%)	0.42	0.04
Drift (%):	0.25	0.29
Aeration Post Run 2 Drift (D ≤ 3% of range)		
Actual Analyzer Response:	0.04	11.98
System Bias (%)	0.46	-0.08
Drift (%):	0.04	0.12
Sterilization Post Run 2 Drift (D ≤ 3% of range)		
Actual Analyzer Response:	0.06	12.02
System Bias (%)	0.54	0.08
Drift (%):	0.08	0.04
Aeration Post Run 3 Drift (D ≤ 3% of range)		
Actual Analyzer Response:	0.04	12.01
System Bias (%)	0.46	0.04
Drift (%):	0.08	0.04
Sterilization Post Run 3 Drift (D ≤ 3% of range)		
Actual Analyzer Response:	0.03	12.02
System Bias (%)	0.42	0.08
Drift (%):	0.04	0.04

Carbon Dioxide

Calibration Gas Standard Concentrations (%) (C_v)		
Zero	Mid	High/Span (CS)
0.00	9.229	18.59

Analyzer Calibration Error (ACE ≤ 2% of range)			
Actual Analyzer Response (C_{Dir}):	0.04	9.28	18.76
Analyzer Cal Error (%)	0.22	0.27	0.91

Initial System Bias (SB ≤ 5% of range)		
	Zero	Bias Gas
Cal Gas Standard Concentration:	0.00	9.229
Actual Analyzer Response (C_s):	0.08	9.24
Initial System Bias (%)	0.22	-0.22
Sterilization Post Run 1 Drift (D ≤ 3% of range)		
Actual Analyzer Response:	0.37	9.53
System Bias (%)	1.78	1.34
Drift (%):	1.56	1.56
Aeration Post Run 1 Drift (D ≤ 3% of range)		
Actual Analyzer Response:	0.36	9.45
System Bias (%)	1.72	0.91
Drift (%):	0.05	0.43
Aeration Post Run 2 Drift (D ≤ 3% of range)		
Actual Analyzer Response:	0.25	9.34
System Bias (%)	1.13	0.32
Drift (%):	0.59	0.59
Sterilization Post Run 2 Drift (D ≤ 3% of range)		
Actual Analyzer Response:	0.21	9.31
System Bias (%)	0.91	0.16
Drift (%):	0.32	0.43
Aeration Post Run 3 Drift (D ≤ 3% of range)		
Actual Analyzer Response:	0.22	9.36
System Bias (%)	0.97	0.43
Drift (%):	0.05	0.27
Sterilization Post Run 3 Drift (D ≤ 3% of range)		
Actual Analyzer Response:	0.29	9.43
System Bias (%)	1.34	0.81
Drift (%):	0.38	0.38

Definitions:

ACE = Analyzer Calibration Error, percent of calibration span

C_{Dir} = Measured concentration of a calibration gas (low, mid, or high) when introduced in direct calibration mode, ppmv or %

C_v = Manufacturer certified concentration of a calibration gas (low, mid, or high), ppmv or %

C_s = Measured concentration of a calibration gas (low, mid, or high) when introduced in system calibration mode, ppmv or %

CS = Calibration span, ppmv or %

D = Drift assessment, percent of calibration span

SB = System bias, percent of calibration span.

SB_i = Pre-run system bias, percent of calibration span.

SB_{final} = Post-run system bias, percent of calibration span.

Equations:

$ACE = ((C_{Dir} - C_v) / CS) * 100\%$

$SB = ((C_s - C_{Dir}) / CS) * 100\%$

$D = |SB_{final} - SB_i|$

M25A QA/QC CE/Drift Calculator

Ethylene Oxide

Analyzer Range (CS)	Calibration Gas Standard Concentrations (ppm) (C_v)			
	Zero	Low	Mid	High
10	0.00	3.140	5.298	8.852

Analyzer Calibration Error (ACE ≤ 5% of cal std)				
Actual Analyzer Response (C_s):	0.01	3.13	5.23	8.87
Analyzer Cal Error (%)	0.10	-0.32	-1.28	-0.92

Sterilization Post Run 1 Drift (D ≤ 3% of range)		
	Zero	Bias Gas
Cal Gas Standard Concentration:	0.00	3.140
Actual Analyzer Response:	0.00	3.09
Drift (%):	0.10	0.40
Aeration Post Run 1 Drift (D ≤ 3% of range)		
Actual Analyzer Response:	0.00	3.17
Drift (%):	0.00	0.80
Aeration Post Run 2 Drift (D ≤ 3% of range)		
Actual Analyzer Response:	0.02	3.17
Drift (%):	0.20	0.00
Sterilization Post Run 2 Drift (D ≤ 3% of range)		
Actual Analyzer Response:	0.02	3.12
Drift (%):	0.00	0.50
Aeration Post Run 3 Drift (D ≤ 3% of range)		
Actual Analyzer Response:	0.00	3.11
Drift (%):	0.20	0.10
Sterilization Post Run 3 Drift (D ≤ 3% of range)		
Actual Analyzer Response:	0.00	3.09
Drift (%):	0.00	0.20

Definitions:

ACE = Analyzer Calibration Error, percent of calibration span

C_s = Measured concentration of a calibration gas (low, mid, or high) when introduced in system calibration mode, ppmv

C_v = Manufacturer certified concentration of a calibration gas (low, mid, or high), ppmv

CS = Calibration span, ppmv

D = Drift assessment, percent of calibration span

Equations:

$ACE = ((C_s - C_v) / CS) * 100\%$

D = ((pre analyzer response - post analyzer response) / CS) * 100%

PACE Environmental
Minute Average

Date	Time	O_2 (%)	CO_2 (%)	THC (ppm)	
12/15/20	7:23:28	-0.07	0.04	0.09	DIRECT ZERO
12/15/20	7:24:27	13.79	10.62	0.06	
12/15/20	7:25:27	24.14	18.85	0.07	
12/15/20	7:26:27	24.06	18.76	0.06	DIRECT HIGH CO2 O2
12/15/20	7:27:27	23.78	18.29	0.06	
12/15/20	7:28:26	13.05	9.01	0.03	
12/15/20	7:29:26	12.00	9.28	0.02	DIRECT MID CO2 O2
12/15/20	7:30:27	14.56	5.88	0.05	
12/15/20	7:31:27	20.97	0.15	0.04	
12/15/20	7:32:27	13.14	0.13	0.07	
12/15/20	7:33:27	0.04	0.07	0.04	
12/15/20	7:34:27	12.11	0.10	0.05	
12/15/20	7:35:26	4.40	0.10	0.02	
12/15/20	7:36:26	0.01	0.08	0.08	
12/15/20	7:37:26	-0.01	0.08	0.06	
12/15/20	7:38:27	-0.01	0.08	0.01	INITIAL BIAS ZERO
12/15/20	7:39:27	2.62	2.51	0.08	
12/15/20	7:40:27	11.95	9.24	0.03	INITIAL BIAS CO2 O2
12/15/20	7:41:27	13.79	7.01	0.05	
12/15/20	7:42:26	8.21	0.51	0.05	
12/15/20	7:43:27	0.01	0.12	0.05	
12/15/20	7:44:26	-0.01	0.12	0.03	
12/15/20	7:45:26	-0.01	0.12	0.02	
12/15/20	7:46:27	-0.01	0.12	0.03	
12/15/20	7:47:26	-0.02	0.12	0.08	
12/15/20	7:48:27	-0.02	0.12	0.03	
12/15/20	7:49:26	-0.02	0.12	0.07	
12/15/20	7:50:27	-0.02	0.12	0.03	
12/15/20	7:51:26	-0.01	0.12	0.05	
12/15/20	7:52:26	-0.02	0.12	0.06	
12/15/20	7:53:27	-0.01	0.14	0.03	
12/15/20	7:54:26	-0.02	0.15	0.19	
12/15/20	7:55:27	-0.02	0.15	3.18	
12/15/20	7:56:26	-0.02	0.16	3.32	
12/15/20	7:57:27	-0.02	0.16	3.16	
12/15/20	7:58:26	-0.02	0.15	3.15	
12/15/20	7:59:26	-0.02	0.15	3.15	
12/15/20	8:00:27	-0.02	0.16	3.24	
12/15/20	8:01:26	-0.02	0.15	3.33	
12/15/20	8:02:26	-0.02	0.15	3.39	
12/15/20	8:03:26	-0.02	0.16	3.47	

Pre Calibrations

Date	Time	O_2 (%)	CO_2 (%)	THC (ppm)	
12/15/20	8:04:27	-0.02	0.16	3.17	
12/15/20	8:05:26	-0.02	0.15	3.17	
12/15/20	8:06:26	-0.02	0.15	3.20	
12/15/20	8:07:26	-0.02	0.15	3.22	
12/15/20	8:08:26	-0.02	0.15	3.19	
12/15/20	8:09:27	-0.02	0.18	3.24	
12/15/20	8:10:26	-0.03	0.19	3.26	
12/15/20	8:11:27	-0.03	0.20	3.29	
12/15/20	8:12:27	-0.02	0.20	3.34	
12/15/20	8:13:26	-0.03	0.20	3.34	
12/15/20	8:14:26	-0.03	0.20	3.11	
12/15/20	8:15:27	-0.03	0.20	3.13	INITIAL BIAS LOW THC
12/15/20	8:16:27	-0.03	0.20	3.10	
12/15/20	8:17:26	8.10	0.32	8.33	
12/15/20	8:18:27	0.31	0.19	5.13	
12/15/20	8:19:27	-0.03	0.21	5.23	INITIAL BIAS MID THC
12/15/20	8:20:26	-0.03	0.23	5.19	
12/15/20	8:21:26	7.02	0.32	9.36	
12/15/20	8:22:27	-0.02	0.23	8.87	INITIAL BIAS HIGH THC
12/15/20	8:23:27	-0.03	0.23	7.09	
12/15/20	8:24:26	13.20	0.43	1.81	
12/15/20	8:25:27	20.53	0.52	0.70	
12/15/20	8:26:27	20.53	0.52	0.67	

PACE Environmental
Minute Average

Date	Time	O_2 (%)	CO_2 (%)	THC (ppm)	
12/15/20	9:00:27	13.00	0.56	1.60	
12/15/20	9:01:27	0.02	0.37	3.09	
12/15/20	9:02:27	-0.01	0.37	3.09	BIAS 1 LOW THC
12/15/20	9:03:27	-0.01	0.38	1.34	
12/15/20	9:04:27	-0.02	0.38	0.06	
12/15/20	9:05:27	-0.03	0.37	0.00	BIAS 1 ZERO
12/15/20	9:06:27	3.32	3.28	0.07	
12/15/20	9:07:26	11.91	9.49	0.00	
12/15/20	9:08:27	11.94	9.53	0.00	BIAS 1 CO2 O2
12/15/20	9:09:26	12.19	9.09	0.12	
12/15/20	9:10:27	19.16	1.46	0.29	
12/15/20	9:11:27	20.56	0.73	0.26	

PACE Environmental
Minute Average

Date	Time	O_2 (%)	CO_2 (%)	THC (ppm)	
12/15/20	11:43:26	0.06	0.36	1.74	
12/15/20	11:44:27	0.04	0.36	3.17	BIAS 2 THC
12/15/20	11:45:27	0.18	0.57	2.36	
12/15/20	11:46:27	11.15	8.92	0.10	
12/15/20	11:47:26	12.01	9.45	0.05	BIAS 2 CO2 O2
12/15/20	11:48:26	8.77	6.62	0.05	
12/15/20	11:49:27	0.06	0.40	0.00	
12/15/20	11:50:26	0.03	0.36	0.00	BIAS 2 ZERO
12/15/20	11:51:26	0.03	0.36	0.00	
12/15/20	11:52:26	9.12	0.50	0.55	

PACE Environmental
Minute Average

Date	Time	O_2 (%)	CO_2 (%)	THC (ppm)	
12/15/20	12:55:27	13.10	0.48	1.98	
12/15/20	12:56:27	0.09	0.24	3.11	
12/15/20	12:57:27	0.06	0.24	3.17	BIAS 3 THC
12/15/20	12:58:27	0.10	0.31	2.51	
12/15/20	12:59:26	0.25	0.36	0.10	
12/15/20	13:00:26	0.04	0.25	0.02	BIAS 3 ZERO
12/15/20	13:01:27	2.97	2.75	0.07	
12/15/20	13:02:27	11.98	9.34	0.08	BIAS 3 CO2 O2
12/15/20	13:03:27	13.35	7.67	0.30	
12/15/20	13:04:27	20.57	0.59	0.66	
12/15/20	13:05:27	20.61	0.55	0.64	

PACE Environmental
Minute Average

Date	Time	O_2 (%)	CO_2 (%)	THC (ppm)	
12/15/20	13:49:27	1.75	0.38	1.32	
12/15/20	13:50:27	0.08	0.21	3.08	
12/15/20	13:51:27	0.07	0.21	3.12	BIAS 4 THC
12/15/20	13:52:27	0.07	0.21	1.74	
12/15/20	13:53:27	0.06	0.21	0.02	BIAS 4 ZERO
12/15/20	13:54:27	5.53	4.63	0.09	
12/15/20	13:55:27	12.02	9.31	0.04	BIAS 4 CO2 O2
12/15/20	13:56:27	13.99	7.05	0.15	
12/15/20	13:57:27	21.04	0.29	0.21	

PACE Environmental
Minute Average

Date	Time	O_2 (%)	CO_2 (%)	THC (ppm)	
12/15/20	16:38:27	0.09	0.21	0.76	
12/15/20	16:39:27	0.06	0.21	2.83	
12/15/20	16:40:27	0.05	0.22	3.11	BIAS 5 THC
12/15/20	16:41:27	0.05	0.22	0.44	
12/15/20	16:42:27	0.04	0.22	0.00	BIAS 5 ZERO
12/15/20	16:43:27	0.04	0.22	0.00	
12/15/20	16:44:27	5.98	4.98	0.06	
12/15/20	16:45:27	12.01	9.36	0.00	BIAS 5 CO2 O2
12/15/20	16:46:27	12.24	9.02	0.27	
12/15/20	16:47:27	20.22	0.81	0.69	

PACE Environmental
Minute Average

Date	Time	O_2 (%)	CO_2 (%)	THC (ppm)	
12/15/20	17:30:27	20.61	0.62	0.98	
12/15/20	17:31:27	5.66	0.62	1.04	
12/15/20	17:32:27	0.06	0.29	3.09	BIAS 6 THC
12/15/20	17:33:27	0.04	0.29	2.20	
12/15/20	17:34:27	0.03	0.29	0.00	BIAS 6 ZERO
12/15/20	17:35:27	0.35	0.68	0.03	
12/15/20	17:36:27	11.46	9.10	0.01	
12/15/20	17:37:27	12.02	9.43	0.00	BIAS 6 CO2 O2
12/15/20	17:38:27	12.03	9.45	0.00	
12/15/20	17:39:27	15.82	5.62	0.04	
12/15/20	17:40:14	20.10	6.93	0.02	

Analyzer Response Time Documentation

Analyzer Response Test

Analyzer Make
Analyzer Model CAI ZRE O2
Analyzer Serial # N5F0123

Methods 7E, 3A, 10
Use Low and High Gases and perform during initial system bias

Perform 2 runs as follows: Run the Low gas. Record the time it takes the Low gas to reach 95% of the value. Repeat the process for the High gas. The response time is dictated by the longest run seen to achieve 95% of the gas value used.

Run #	Gas Type	Response Time
1	N2	25
1	24-02 O2	35
2		35
2		40

System Response Time [ ]

Analyzer Response Test

Analyzer Make CAI ZRE CO2
Analyzer Model
Analyzer Serial # N5T0123

Methods 7E, 3A, 10
Use Low and High Gases and perform during initial system bias

Perform 2 runs as follows: Run the Low gas. Record the time it takes the Low gas to reach 95% of the value. Repeat the process for the High gas. The response time is dictated by the longest run seen to achieve 95% of the gas value used.

Run #	Gas Type	Response Time
1	N2	35
1	18.59 CO2	75
2		35
2		35

System Response Time

Analyzer Response Test

Analyzer Make VIG 200 THC
Analyzer Model
Analyzer Serial # 515712

Methods 25A & B
Use Zero and High Gases and perform during initial system bias

Perform 3 runs as follows: Run Zero (N2) gas until the analyzer stabilizes, then quickly switch to high gas. Record the time it takes the high gas to reach 95% of the value.

Run #	Gas Type	Response Time
1	8.952 E70	20
2		20
3		20

Avg Response Time

Analyzer Interference Check Documentation

Method 7E-Interfernce Response

Applies to Models: 600 Series NDIR/PMD, 100/200/300 Series NDIR/PMD, ZRE w/PMD
Date of Test: 1/26/2011
Analyzer Type: PMD
Model: 602-P
Serial Numer: U09018-M
Calibration Span: 20.7% O2, balance N2

Test Gas	Interfernt Concentration	Zero Response	Span Response	Interferent Response
SO2	513 ppm	0.000%	0.020%	0.020%
H2O	0.82%	0.015%	0.020%	0.020%
N2O	10.00 ppm	0.000%	0.000%	0.000%
NO	94.9 ppm	0.000%	0.000%	0.000%
NO2	99.8 ppm	0.000%	0.000%	0.000%
CO	900 ppm	0.000%	0.000%	0.000%
CH4	90.9 ppm	0.000%	0.000%	0.000%
HCl	27.99ppm	0.000%	0.000%	0.000%
Sum of Responses				0.004%
% of Calibration Span				0.019%

Method 7E-Interfernce Response

Applies to Models: 600 Series NDIR, 100/200/300 Series NDIR, ZRE
Date of Test: 1/26/2011
Analyzer Type: NDIR
Model: 602-P
Serial Numer: U09018-M
Calibration Span: 20.2% CO_2/Balance N_2

Test Gas	Interfernt Concentration	Zero Response	Span Response	Interferent Response
SO2	102.6 ppm	0.000%	0.000%	0.000%
H2O	0.82%	0.055%	0.055%	0.055%
N2O	10.00 ppm	0.005%	0.010%	0.010%
NO	94.9 ppm	0.005%	0.025%	0.025%
NO2	99.8 ppm	0.010%	0.010%	0.010%
CO	100.0 ppm	0.010%	0.010%	0.010%
CH4	101.0 ppm	0.010%	0.010%	0.010%
HCl	27.99ppm	0.010%	0.010%	0.010%
Sum of Responses				0.013%
% of Calibration Span				0.064%

Calibration Gas Certificates

Bottle Manifest & Range Confirmation

Range	25% - 35%	45% - 55%	80%	90%
0 - 1%	0.25 - 0.35	0.45 - 0.55	0.80	0.90
0 - 2%	0.50 - 0.70	0.90 - 1.10	1.60	1.80
0 - 5%	1.25 - 1.75	2.25 - 2.75	4.00	4.50
0 - 20%	5.00 - 7.00	9.00 - 11.00	16.00	18.00
0 - 60%	14.98 - 20.97	26.96 - 32.95	47.92	53.91

Range	25% - 35%	45% - 55%	80% - 90%
0 - 50 ppm	12.5 - 17.5	22.5 - 27.5	40 - 45
0 - 300 ppm	75 - 105	135 - 165	240 - 270
0 - 600 ppm	150 - 210	270 - 330	480 - 540
0 - 800 ppm	200 - 280	360 - 440	640 - 720
0 - 2000 ppm	500 - 700	900 - 1100	1600 - 1800
0 - 5000 ppm	1250 - 1750	2250 - 2750	4000 - 4500
0 - 10000 ppm	2500 - 3500	4500 - 5500	8000 - 9000

CO2 / O2 / NOX / SO2 / CO				
	RATA/Stack Test	CGA Pollutant	CGA O2	CGA CO2
High bottle	sets range	n/a	n/a	n/a
Mid bottle	40-60% high bottle	50-60% range	8-12%	10-14%
Low bottle	zero gas	20-30% range	4-6%	5-8%

Customer: B. Braun

Date: 12/11/2020

	Bottle #	Gas Value	UN #	Class	Expiration Date	Start PSI	End PSI	Regulator #
1	EB0091033	N2	1066	2		600	500	
2	CC113434	18.59/24.02 CO2/O2	1956	2		1600	1500	
3	CC215297	11.42/9.229 O2/CO2	1956	2		1500	1300	
4	CC733138	3.140 ETHOX	1956	2		2000	1400	
5	CC734295	5.298 ETHOX	1956	2		2000	1900	
6	CC734294	8.952 ETHOX	1956	2		2000	1900	
7	CC00855B	Air	1002	2		1000	MT	
8	ALM049313	H2	1049	2		1200	1100	
9	XC01546IB	N2	1066	2		1800	1700	
10								
11								
12								
13								
14								
15								
16								

Airgas - Chemtrec - 1 800 424 9300
Praxair - Chemtrec - 1 800 424 9300
Liquid Tech - Chemtel - 1 800 255 3924

Airgas
an Air Liquide company

Airgas Specialty Gases
Airgas USA, LLC
6141 Easton Road
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Plumsteadville, PA 18949
Airgas.com

CERTIFICATE OF BATCH ANALYSIS

Grade of Product: CEM-CAL ZERO

Part Number:	NI CZ15A	Reference Number:	160-401871681-1
Cylinder Analyzed:	CC715535	Cylinder Volume:	142.0 CF
Laboratory:	124 - Plumsteadville - PA	Cylinder Pressure:	2000 PSIG
Analysis Date:	Aug 05, 2020	Valve Outlet:	580
Lot Number:	160-401871681-1		

Expiration Date: Aug 05, 2028

ANALYTICAL RESULTS

Component		Requested Purity		Certified Concentration
NITROGEN		99.9995 %		99.9995 %
CARBON DIOXIDE	<	1.0 PPM	<LDL	0.03 PPM
NOx	<	0.1 PPM	<LDL	0.02 PPM
SO2	<	0.1 PPM	<LDL	0.02 PPM
THC	<	0.1 PPM	<LDL	0.03 PPM
CARBON MONOXIDE	<	0.5 PPM		0.165 PPM

Permanent Notes: Airgas certifies that the contents of this cylinder meet the requirements of 40 CFR 72.2

Cylinders in Batch:

ALM018038, ALM025957, ALM045320, ALM046684, ALM054065, ALM057380, CC114910, CC138957, CC17355, CC193212, CC401985, CC412860, CC482572, CC501937, CC503602, CC709870, CC715535, CC75111, CC80842, EB0091033, EB0113053, SG9101576, SG9159620BAL, XC033769B

Impurities verified against analytical standards traceable to NIST by weight and/or analysis.

Approved for Release

Airgas
an Air Liquide company

Airgas Specialty Gases
Airgas USA, LLC
6141 Easton Road
Bldg 1
Plumsteadville, PA 18949
Airgas.com

CERTIFICATE OF ANALYSIS

Grade of Product: EPA Protocol

Part Number:	E03NI79E15A00E4	Reference Number:	160-401903519-1
Cylinder Number:	CC215297	Cylinder Volume:	150.5 CF
Laboratory:	124 - Plumsteadville - PA	Cylinder Pressure:	2015 PSIG
PGVP Number:	A12020	Valve Outlet:	590
Gas Code:	CO2,O2,BALN	Certification Date:	Sep 15, 2020

Expiration Date: Sep 15, 2028

Certification performed in accordance with "EPA Traceability Protocol for Assay and Certification of Gaseous Calibration Standards (May 2012)" document EPA 600/R-12/531, using the assay procedures listed. Analytical Methodology does not require correction for analytical interference. This cylinder has a total analytical uncertainty as stated below with a confidence level of 95%. There are no significant impurities which affect the use of this calibration mixture. All concentrations are on a mole/mole basis unless otherwise noted.

Do Not Use This Cylinder below 100 psig, i.e. 0.7 megapascals.

ANALYTICAL RESULTS

Component	Requested Concentration	Actual Concentration	Protocol Method	Total Relative Uncertainty	Assay Dates
CARBON DIOXIDE	9.000 %	9.229 %	G1	+/- 0.5% NIST Traceable	09/15/2020
OXYGEN	12.00 %	11.92 %	G1	+/- 0.3% NIST Traceable	09/15/2020
NITROGEN	Balance				

CALIBRATION STANDARDS

Type	Lot ID	Cylinder No	Concentration	Uncertainty	Expiration Date
NTRM	102505	K025852	7.016 % CARBON DIOXIDE/NITROGEN	+/- 0.5%	Jan 13, 2022
NTRM	10010602	1D38055	9.967 % OXYGEN/NITROGEN	+/- 0.3%	Apr 19, 2022

ANALYTICAL EQUIPMENT

Instrument/Make/Model	Analytical Principle	Last Multipoint Calibration
HORIBA VA5011 T5V6VU9P NDIR CO2	NDIR	Sep 09, 2020
SIEMENS OXYMAT 6 - N1-W5-951 - O2	PARAMAGNETIC	Sep 01, 2020

Triad Data Available Upon Request

Airgas
an Air Liquide company

Airgas Specialty Gases
Airgas USA, LLC
600 Union Landing Road
Cinnaminson, NJ 08077-0000
Airgas.com

CERTIFICATE OF ANALYSIS

Grade of Product: EPA Protocol

Part Number:	E03NI57E15A37E3	Reference Number:	82-401390363-1
Cylinder Number:	CC113434	Cylinder Volume:	159.3 CF
Laboratory:	124 - Riverton (SAP) - NJ	Cylinder Pressure:	2015 PSIG
PGVP Number:	B52019	Valve Outlet:	296
Gas Code:	CO2,O2,BALN	Certification Date:	Jan 10, 2019

Expiration Date: Jan 10, 2027

Certification performed in accordance with "EPA Traceability Protocol for Assay and Certification of Gaseous Calibration Standards (May 2012)" document EPA 600/R-12/531, using the assay procedures listed. Analytical Methodology does not require correction for analytical interference. This cylinder has a total analytical uncertainty as stated below with a confidence level of 95%. There are no significant impurities which affect the use of this calibration mixture. All concentrations are on a volume/volume basis unless otherwise noted.

Do Not Use This Cylinder below 100 psig, i.e. 0.7 megapascals.

ANALYTICAL RESULTS

Component	Requested Concentration	Actual Concentration	Protocol Method	Total Relative Uncertainty	Assay Dates
CARBON DIOXIDE	19.00 %	18.59 %	G1	+/- 0.8% NIST Traceable	01/09/2019
OXYGEN	24.00 %	24.02 %	G2	+/- 0.5% NIST Traceable	01/10/2019
NITROGEN	Balance				

CALIBRATION STANDARDS

Type	Lot ID	Cylinder No	Concentration	Uncertainty	Expiration Date
NTRM	13060731	CC413777	16.939 % CARBON DIOXIDE/NITROGEN	+/- 0.6%	May 08, 2019
NTRM	09061420	CC273671	22.53 % OXYGEN/NITROGEN	+/- 0.4%	Mar 08, 2019

ANALYTICAL EQUIPMENT

Instrument/Make/Model	Analytical Principle	Last Multipoint Calibration
Horiba VIA 510-CO2-19GYCXEG	NDIR	Jan 04, 2019
Horiba MPA 510-O2-7TWMJ041	Paramagnetic	Jan 04, 2019

Triad Data Available Upon Request

C. [signature]

Approved for Release

Airgas
an Air Liquide company

Airgas Specialty Gases
Airgas USA, LLC
6141 Easton Road
Bldg 1
Plumsteadville, PA 18949
Airgas.com

CERTIFICATE OF ANALYSIS

Grade of Product: CERTIFIED STANDARD-SPEC

Customer:	PACE ENVIRONMENTAL PRODUCTS		
Part Number:	X02NI99C15AJ846	Reference Number:	160-401938392-1
Cylinder Number:	CC733138	Cylinder Volume:	144.3 Cubic Feet
Laboratory:	124 - Plumsteadville - PA	Cylinder Pressure:	2015 PSIG
Analysis Date:	Oct 29, 2020	Valve Outlet:	350
Lot Number:	160-401938392-1		

Expiration Date: Oct 29, 2021

Product composition verified by direct comparison to calibration standards traceable to N.I.S.T. weights and/or N.I.S.T. Gas Mixture reference materials.

ANALYTICAL RESULTS

Component	Req Conc	Actual Concentration (Mole %)	Analytical Uncertainty
ETHYLENE OXIDE	3.000 PPM	3.140 PPM	+/- 5%
NITROGEN	Balance		

Approved for Release

Airgas
an Air Liquide company

Airgas Specialty Gases
Airgas USA, LLC
6141 Easton Road
Bldg 1
Plumsteadville, PA 18949
Airgas.com

CERTIFICATE OF ANALYSIS

Grade of Product: CERTIFIED STANDARD-SPEC

Customer:	PACE ENVIRONMENTAL PRODUCTS		
Part Number:	X02NI99C15A0047	Reference Number:	160-401938393-1
Cylinder Number:	CC734295	Cylinder Volume:	144.3 Cubic Feet
Laboratory:	124 - Plumsteadville - PA	Cylinder Pressure:	2015 PSIG
Analysis Date:	Oct 29, 2020	Valve Outlet:	350SS
Lot Number:	160-401938393-1		

Expiration Date: Oct 29, 2021

Product composition verified by direct comparison to calibration standards traceable to N.I.S.T. weights and/or N.I.S.T. Gas Mixture reference materials.

ANALYTICAL RESULTS

Component	Req Conc	Actual Concentration (Mole %)	Analytical Uncertainty
ETHYLENE OXIDE	5.000 PPM	5.298 PPM	+/- 5%
NITROGEN	Balance		

Approved for Release

Airgas
an Air Liquide company

Airgas Specialty Gases
Airgas USA, LLC
6141 Easton Road
Bldg 1
Plumsteadville, PA 18949
Airgas.com

CERTIFICATE OF ANALYSIS

Grade of Product: PRIMARY STANDARD

Customer:	PACE RNVIRONMENTAL PRODUCTS		
Part Number:	X02NI99P15A0619	Reference Number:	160-401938394-1
Cylinder Number:	CC734294	Cylinder Volume:	144.3 Cubic Feet
Laboratory:	124 - Plumsteadville - PA	Cylinder Pressure:	2015 PSIG
Analysis Date:	Oct 29, 2020	Valve Outlet:	350SS
Lot Number:	160-401938394-1		

Expiration Date: Oct 29, 2021

Primary Standard Gas Mixtures are traceable to N.I.S.T. weights and/or N.I.S.T. Gas Mixture reference materials.

ANALYTICAL RESULTS

Component	Req Conc	Actual Concentration (Mole %)	Analytical Uncertainty
ETHYLENE OXIDE	8.500 PPM	8.952 PPM	+/- 1%
NITROGEN	Balance		

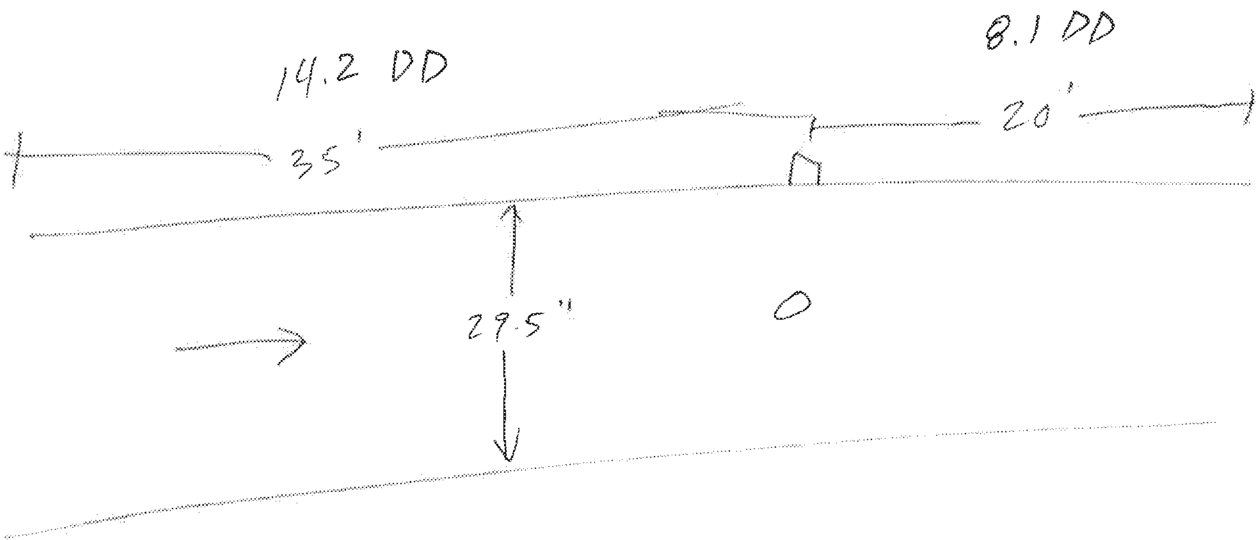
Approved for Release

APPENDIX E

FIELD SHEETS

BBRAUN 12/15/20

CAT OX OUTLET



Traverse Point Calculator

Project:	B. Braun Outlet Sampling Location		
Stack Diameter:			29.5
Number of Points Needed in Each Port:			8
Sample Train:			Flow

Port Extention =

Distance from Stack Wall (inches):	Calculated Points			Points with Port Extension		
Point 1			0.9			0.9
2			3.1			3.1
3			5.7			5.7
4			9.5			9.5
5			20.0			20.0
6			23.8			23.8
7			26.4			26.4
8			28.6			28.6
9						
10						
11						
12						

Stratification Check
4.9
14.8
24.6

Stack Cross Sectional Area

4.746

U.S. EPA Method 1 Traverse Point Percentages

# of Points	4	6	8	10	12
	0.067	0.044	0.032	0.026	0.021
	0.25	0.146	0.105	0.082	0.067
	0.75	0.296	0.194	0.146	0.118
	0.933	0.704	0.323	0.226	0.177
		0.854	0.677	0.342	0.25
		0.956	0.806	0.658	0.356
			0.895	0.774	0.644
			0.968	0.854	0.75
				0.918	0.823
				0.974	0.882
					0.933
					0.979

BBRAUN
CATOX OUTLET
12/14/20

Cyclonic Flow Check

RUN #	
Location:	
Date:	
Start Time:	
End Time:	

RUN DATA

R_{ADO}: ______ degrees
R_{SLO}: ______ degrees

Carbon Dioxide (%) [CO2] ______
Oxygen (%) [O2] ______
Methane (%) [CH4] ______
Moisture (%) [Bws] ______
Stack Static Pressure ("H2O) [Ps] ______
Barometric Pressure ("Hg) [Pb] ______

TRAVERSE DATA

Port/Point	(Reading) Yaw Angle (deg)	P1-P2 (in H_20)	P4-P5 (in H_20)	Stack Temp (deg F)
A1	2			
2	2			
3	0			
4	0			
5	0			
6	0			
7	0			
8	0			
B1	4			
2	3			
3	1			
4	0			
5	0			
6	0			
7	1			
8	1			

Method 2 FLOW DATA SHEET

Project No. BBRANN
Proj. Name

Site Location BETHLEHEM, PA
Unit/Location STEPHENSON (?)
Stack ID 29.5

MB / Manometer # MB04
Pitot Tube / Probe ID # 6-1
(circle one)

Operator(s) BG
Baro. Pressure 30.31

Start Time		Stop Time	
Date	Leak Check	WB	
12/15/20	PRE ✓		
RUN #	POST ✓	DB	
PRELIM	STATIC		
	-2.7	Stack	
Real Time	Traverse Pt.	Delta P	Temp. (°F)
	A1	1.0	
	2	1.1	
	3	1.3	
	4	1.3	
	5	1.3	
	6	1.2	
	7	1.2	
	8	1.1	
	B1	0.76	
	2	1.1	
	3	1.2	
	4	1.2	
	5	1.2	
	6	1.2	
	7	1.2	
	8	1.0	

AVERAGE 1.148

Start Time		Stop Time	
Date	Leak Check	WB	
	PRE		
RUN #	POST	DB	
	STATIC		
		Stack	
Real Time	Traverse Pt.	Delta P	Temp. (°F)

USED POINT A7

Start Time		Stop Time	
Date	Leak Check	WB	
	PRE		
RUN #	POST	DB	
	STATIC		
		Stack	
Real Time	Traverse Pt.	Delta P	Temp. (°F)

Start Time		Stop Time	
Date	Leak Check	WB	
	PRE		
RUN #	POST	DB	
	STATIC		
		Stack	
Real Time	Traverse Pt.	Delta P	Temp. (°F)

Method 2 FLOW DATA SHEET

Project No. B. Braun
Proj. Name

Site Location Bethlehem, PA
Unit/Location Sterilization
Stack ID 24.5

MB / Manometer # M B04
Pitot Tube / Probe ID # C-1
(circle one)

Operator(s) LR
Baro. Pressure 30.31

Start Time		Stop Time	
Date	Leak Check	WB	
12/15/20	PRE ✓		
RUN #	POST ✓	DB	
1	STATIC		
	-2.7	Stack	
Real Time	Mins Traverse Pt.	Delta P	Temp. (°F)
0836	0	1.2	174
	1	1.2	174
	2	1.2	174
	3	1.2	175
	4	1.2	175
	5	1.1	175
	6	1.2	176
	7	1.2	175
	8	1.2	176
	9	1.2	177
	10	1.2	178
	11	1.2	179
	12	1.2	180
	13	1.2	182
	14	1.1	183
	15	1.2	183
	16	1.2	185
	17	1.2	186
	18	1.2	187
	19	1.2	189
	20	1.2	189
	21	1.2	189
0858	22	1.2	189
	23		
	24		
	25		

Start Time		Stop Time	
Date	Leak Check	WB	
	PRE ✓		
RUN #	POST ✓	DB	
2	STATIC		
	-2.8	Stack	
Real Time	Min Traverse Pt.	Delta P	Temp. (°F)
1310	0	1.2	174
	1	1.2	174
	2	1.2	175
	3	1.2	174
	4	1.2	175
	5	1.2	175
	6	1.2	175
	7	1.2	176
	8	1.2	177
	9	1.2	178
	10	1.2	179
	11	1.2	181
	12	1.2	182
	13	1.2	183
	14	1.2	184
	15	1.2	185
	16	1.2	186
	17	1.2	188
	18	1.2	188
	19	1.2	189
	20	1.2	189
	21	1.2	189
1332	22	1.2	189
	23		
	24		
	25		

Start Time		Stop Time	
Date	Leak Check	WB	
	PRE ✓		
RUN #	POST ✓	DB	
3	STATIC		
	-3.0	Stack	
Real Time	Min Traverse Pt.	Delta P	Temp. (°F)
1709	0	1.6	174
	1	1.6	174
	2	1.6	175
	3	1.6	175
	4	1.6	176
	5	1.6	176
	6	1.6	177
	7	1.6	177
	8	1.6	178
	9	1.6	178
	10	1.6	178
	11	1.6	179
	12	1.6	180
	13	1.6	181
	14	1.6	182
	15	1.6	183
	16	1.6	184
	17	1.6	185
	18	1.6	186
	19	1.6	186
	20	1.6	187
1730	21	1.6	187
	22		
	23		
	24		
	25		

Start Time		Stop Time	
Date	Leak Check	WB	
	PRE		
RUN #	POST	DB	
	STATIC		
		Stack	
Real Time	Traverse Pt.	Delta P	Temp. (°F)

Method 4 MOISTURE DATA SHEET

Project # B. Braun
Proj. Name
Date 12/15/2020
Site Loc. Bethlehem, PA
Unit/Loc. Sterilization

Meter Box # MB04
Delta Y @ 1.014
Delta H @ 1.73
MB Pump # MB04
Stack ID 29.5

Operator(s) LR
Run 1 Baro. Press. 30.31
Run 2 Baro. Press. 30.31
Run 3 Baro. Press. 30.35

RUN # 1

MOISTURE TRAIN — Start Time 836 — Stop Time 906 — Impingers ICED ? ✓

Real Time	Sampling Time	Dry Gas Meter VOLUME (ft³)	Delta H	In.Temp. (°F)	Out Temp.(°F)	EXIT Impinger Temp.(°F)	Pump Vacuum ("Hg)
836	0	38.785	2.0	73	73	36	-1
	5	42.7	2.0	76	73	36	-1
	10	46.7	2.0	81	73	36	-1
	15	50.7	2.0	85	74	37	-2
	20	54.6	2.0	89	75	38	-2
	25	58.55	2.0	91	76	38	-2
906	30	62.520	–	–	–	–	–

Train Leak Check

PRE CFM@	PRE VAC	POST CFM@	POST VAC
0.001	@ 15"	0.001	@ 5"

Imp. #	Initial	Final	Diff.
1	734.0	771.1	
2	726.0	691.2	
3	657.3	658.1	
4	959.7	963.1	
5			
6			
7			
8			
9			
T			

RUN # 2

MOISTURE TRAIN — Start Time 1310 — Stop Time 1340 — Impingers ICED ? ✓

Real Time	Sampling Time	Dry Gas Meter VOLUME (ft³)	Delta H	In.Temp. (°F)	Out Temp.(°F)	EXIT Impinger Temp.(°F)	Pump Vacuum ("Hg)
1310	0	131.155	2.0	97	96	46	-1
	5	135.0	2.0	103	96	42	-1
	10	139.1	2.0	107	96	41	-1
	15	143.0	2.0	110	96	42	-2
	20	147.1	2.0	111	97	43	-2
	25	151.1	2.0	112	98	43	-2
1340	30	155.020	–	–	–	–	–

Train Leak Check

PRE CFM@	PRE VAC	POST CFM@	POST VAC
0.001	@ 15"	0.001	@ 5"

Imp. #	Initial	Final	Diff.
1	773.6	776.7	
2	690.6	692.2	
3	657.3	658.5	
4	966.0	970.9	
5			
6			
7			
8			
9			
T			

RUN # 3

MOISTURE TRAIN — Start Time 1709 — Stop Time 1739 — Impingers ICED ? ✓

Real Time	Sampling Time	Dry Gas Meter VOLUME (ft³)	Delta H	In.Temp. (°F)	Out Temp.(°F)	EXIT Impinger Temp.(°F)	Pump Vacuum ("Hg)
1709	0	189.380	2.0	90	91	40	-1
	5	193.35	2.0	95	90	39	-1
	10	197.3	2.0	98	91	38	-2
	15	201.25	2.0	102	91	36	-2
	20	205.2	2.0	108	92	36	-2
	25	209.2	2.0	110	93	36	-2
1739	30	213.212	–	–	–	–	–

Train Leak Check

PRE CFM@	PRE VAC	POST CFM@	POST VAC
0.001	@ 15"	0.001	@ 5"

Imp. #	Initial	Final	Diff.
1	776.7	779.6	
2	692.2	693.7	
3	658.5	659.7	
4	970.9	975.6	
5			
6			
7			
8			
9			
T			

Method 4 MOISTURE DATA SHEET

Project # B. Braun
Proj. Name
Date 12/15/2020
Site Loc. Bethlehem, PA
Unit/Loc. Aeration

Meter Box # MB04
Delta Y @ 1.014
Delta H @ 1.73
MB Pump # MBP04
Stack ID 29.5

Operator(s) LR
Run 1 Baro. Press. 30.31
Run 2 Baro. Press. 30.31
Run 3 Baro. Press. 30.35

RUN # 1	MOISTURE TRAIN				Start Time ~~1040~~ 1042 LR	Stop Time 1142	Impingers ICED ? ✓			
Real Time	Sampling Time	VOLUME (ft³)	Delta H	In.Temp. (°F)	Out Temp. (°F)	EXIT Impinger Temp. (°F)	Pump Vacuum ("Hg)	Train Leak Check		
1042 LR ~~1040~~	0	62.770	1.0	80	79	37	~1	PRE CFM@ VAC	POST CFM@ VAC	
	5	65.6	1.0	82	79	37	~1	0.001 @ 15"	0.001 @ 4"	
	10	68.5	1.0	84	79	36	~1	Imp. #	Initial	Final
	15	71.3	1.0	88	80	36	~1	1	771.1	773.6
	20	74.05	1.0	90	80	37	~1	2	691.2	690.6
	25	76.8	1.0	93	81	37	~1	3	658.1	657.3
	30	79.6	1.0	95	82	38	~1	4	963.1	966.0
	35	82.4	1.0	97	84	38	~1	5		
	40	85.25	1.0	98	85	39	~1	6		
	45	88.1	1.0	99	85	40	~1	7		
	50	90.9	1.0	100	87	40	~1	8		
	55	93.7	1.0	102	88	40	~1	9		
1142	60	96.540	—	—	—	—	—	T		

RUN # 2	MOISTURE TRAIN				Start Time 1155	Stop Time 1255	Impingers ICED ? ✓			
Real Time	Sampling Time	VOLUME (ft³)	Delta H	In.Temp. (°F)	Out Temp. (°F)	EXIT Impinger Temp. (°F)	Pump Vacuum ("Hg)	Train Leak Check		
1155	0	96.715	1.0	92	91	44	~1	PRE CFM@ VAC	POST CFM@ VAC	
	5	99.55	1.0	96	90	43	~1	0.001 @ 15	0.001 @ 4"	
	10	102.4	1.0	99	90	42	~1	Imp. #	Initial	Final
	15	105.3	1.0	101	90	40	~1	1	716.3	720.7
	20	108.1	1.0	102	91	40	~1	2	719.2	720.0
	25	111.0	1.0	104	92	41	~1	3	639.1	639.8
	30	113.85	1.0	105	92	41	~1	4	961.1	965.9
	35	116.7	1.0	106	93	41	~1	5		
	40	119.55	1.0	106	94	42	~1	6		
	45	122.4	1.0	107	94	41	~1	7		
	50	125.25	1.0	107	94	42	~1	8		
	55	128.1	1.0	108	95	42	~1	9		
1255	60	130.925	—	—	—	—	—	T		

RUN # 3	MOISTURE TRAIN				Start Time 1535	Stop Time 1635	Impingers ICED ? ✓			
Real Time	Sampling Time	VOLUME (ft³)	Delta H	In.Temp. (°F)	Out Temp. (°F)	EXIT Impinger Temp. (°F)	Pump Vacuum ("Hg)	Train Leak Check		
1535	0	155.275	1.0	86	87	43	~1	PRE CFM@ VAC	POST CFM@ VAC	
	5	158.1	1.0	86	86	39	~1	0.001 @ 15"	0.001 @ 4"	
	10	160.95	1.0	89	85	38	~1	Imp. #	Initial	Final
	15	163.8	1.0	92	85	39	~1	1	720.7	722.4
	20	166.6	1.0	94	86	39	~1	2	720.0	719.9
	25	169.4	1.0	96	86	40	~1	3	639.8	639.8
	30	172.2	1.0	98	87	40	~1	4	965.9	969.8
	35	175.0	1.0	100	88	40	~1	5		
	40	177.8	1.0	101	89	40	~1	6		
	45	180.65	1.0	102	90	40	~1	7		
	50	183.45	1.0	103	90	40	~1	8		
	55	186.3	1.0	104	91	40	~1	9		
1635	60	189.100	—	—	—	—	—	T		

APPENDIX F

STRATIFICATION CHECK

STRATIFICATION CHECK

Customer Name: B Braun
Site Location: Allentown, PA
Source: CatOx Outlet
Date: 12/15/20

Point	O_2 Concentration (%) (A)	Deviation (% of mean) (B)	Deviation (difference from mean) (C)
1	20.25	0.2	0.0
2	20.27	0.2	0.0
3	20.38	0.4	0.1

Average Response (D) = 20.3
Maximum (% of Mean) (B) = 0.4 %
Maximum (diff from Mean) (C) = 0.1 % diff

Equations:
B = A- D/ D*100
C (diluent) = A- D

ALLOWABLE:	**B ≤ 5% of mean OR**
(single point sampling)	**C (diluent) ≤ 0.3% diff**

ALLOWABLE:	**B ≤ 10% of mean OR**
(3 point sampling)	**C (diluent) ≤ 0.5% diff**

NOTE: If >10% stratification, 12 point sampling must be done; Sampling points selected according to Method 1- Table 1-2.

PACE Environmental
Minute Average

Date	Time	O_2 (%)		
12/15/20	8:36:26	20.57		
12/15/20	8:37:26	20.43		
12/15/20	8:38:27	20.30		
12/15/20	8:39:26	20.25		
12/15/20	8:40:27	20.24		
12/15/20	8:41:26	20.26	**Pt. 1**	**20.25**
12/15/20	8:42:27	20.25		
12/15/20	8:43:26	20.26		
12/15/20	8:44:26	20.25		
12/15/20	8:45:27	20.26		
12/15/20	8:46:26	20.29	**Pt. 2**	**20.27**
12/15/20	8:47:26	20.32		
12/15/20	8:48:26	20.34		
12/15/20	8:49:27	20.35		
12/15/20	8:50:26	20.39		
12/15/20	8:51:26	20.41	**Pt. 3**	**20.38**
12/15/20	8:52:26	20.43		

APPENDIX G

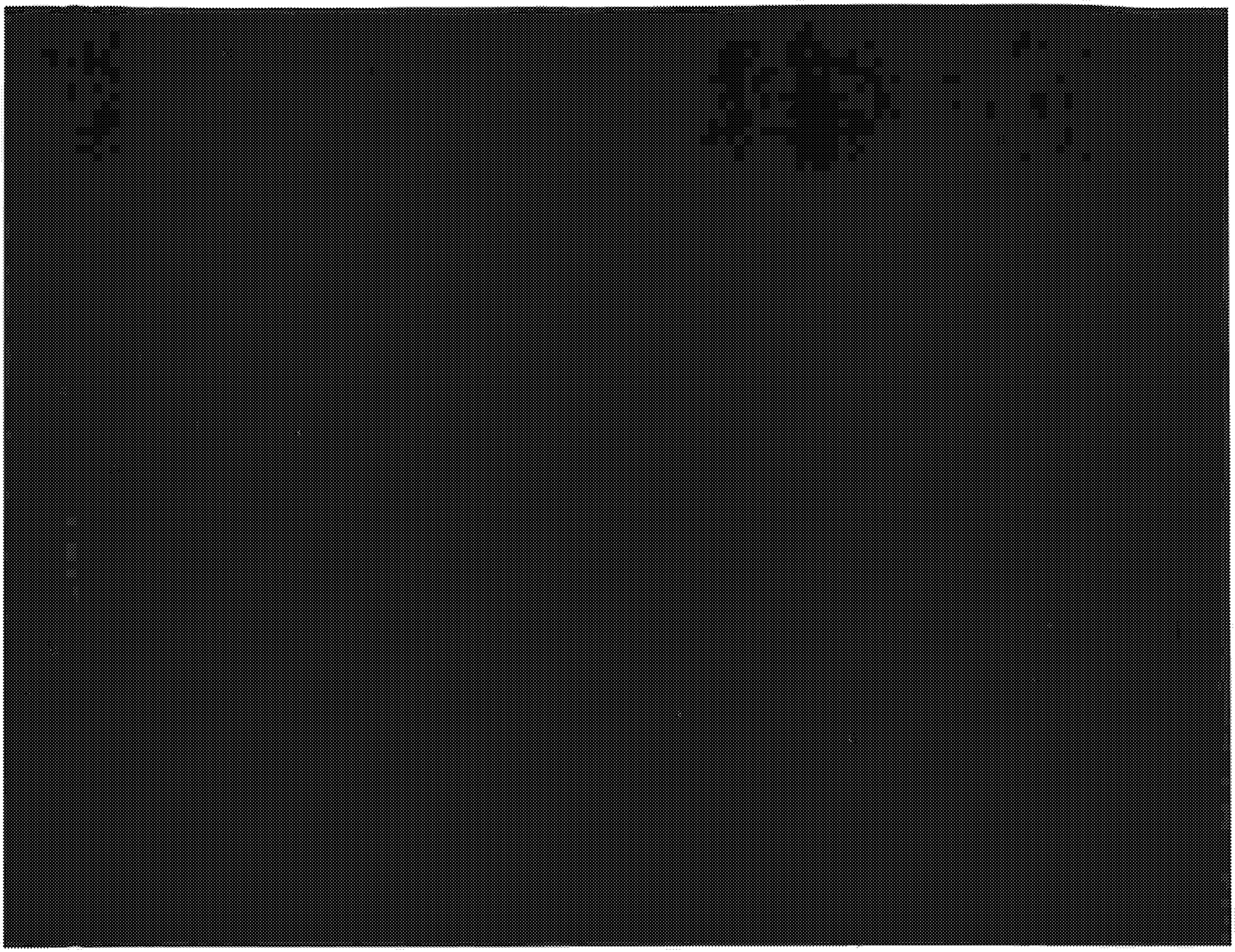
EtO GAS CERTIFICATE & RECORDED PROCESS DATA

[redacted]

Q.A. Reviewed
By LM 12·8·2020

Customer Comments:

This Certificate is computer generated. No signature is required.



BM 12-8-2020

~~BM 8~~

Q.A. Reviewed
By BM 12-8-2020

Sterilization Run 1

gas charge ([redacted] lbs)					
Date	Time	Temp	Pressure	TE121 (CatOx Inlet)	TE124 (CatOx Outlet)
		degrees C	psia	degrees F	degrees F
12/15/20	8:36 AM	[redacted]	[redacted]	310	317
12/15/20	8:37 AM	[redacted]	[redacted]	308	317
12/15/20	8:38 AM	[redacted]	[redacted]	311	317
12/15/20	8:39 AM	[redacted]	[redacted]	311	318
12/15/20	8:40 AM	[redacted]	[redacted]	312	319
12/15/20	8:41 AM	[redacted]	[redacted]	310	321
12/15/20	8:42 AM	[redacted]	[redacted]	309	324
12/15/20	8:43 AM	[redacted]	[redacted]	310	331
12/15/20	8:44 AM	[redacted]	[redacted]	312	338
12/15/20	8:45 AM	[redacted]	[redacted]	314	344
12/15/20	8:46 AM	[redacted]	[redacted]	316	350
12/15/20	8:47 AM	[redacted]	[redacted]	317	355
12/15/20	8:48 AM	[redacted]	[redacted]	316	360
12/15/20	8:49 AM	[redacted]	[redacted]	316	365
12/15/20	8:50 AM	[redacted]	[redacted]	317	369
12/15/20	8:51 AM	[redacted]	[redacted]	317	373
12/15/20	8:52 AM	[redacted]	[redacted]	316	376
12/15/20	8:53 AM	[redacted]	[redacted]	316	378
12/15/20	8:54 AM	[redacted]	[redacted]	315	380
12/15/20	8:55 AM	[redacted]	[redacted]	314	381
12/15/20	8:56 AM	[redacted]	[redacted]	314	382
12/15/20	8:57 AM	[redacted]	[redacted]	314	382
Averages		[redacted]	[redacted]	**313.4**	**349.9**

Sterilization Run 2

gas charge ([redacted]lbs)					
Date	Time	Temp	Pressure	TE121 (CatOx Inlet)	TE124 (CatOx Outlet)
		degrees C	psia	degrees F	degrees F
12/15/20	1:10 PM	[redacted]	[redacted]	308	321
12/15/20	1:11 PM	[redacted]	[redacted]	310	321
12/15/20	1:12 PM	[redacted]	[redacted]	310	321
12/15/20	1:13 PM	[redacted]	[redacted]	310	321
12/15/20	1:14 PM	[redacted]	[redacted]	310	321
12/15/20	1:15 PM	[redacted]	[redacted]	311	322
12/15/20	1:16 PM	[redacted]	[redacted]	311	325
12/15/20	1:17 PM	[redacted]	[redacted]	310	331
12/15/20	1:18 PM	[redacted]	[redacted]	311	338
12/15/20	1:19 PM	[redacted]	[redacted]	313	346
12/15/20	1:20 PM	[redacted]	[redacted]	315	353
12/15/20	1:21 PM	[redacted]	[redacted]	316	359
12/15/20	1:22 PM	[redacted]	[redacted]	316	364
12/15/20	1:23 PM	[redacted]	[redacted]	316	368
12/15/20	1:24 PM	[redacted]	[redacted]	317	373
12/15/20	1:25 PM	[redacted]	[redacted]	316	377
12/15/20	1:26 PM	[redacted]	[redacted]	316	380
12/15/20	1:27 PM	[redacted]	[redacted]	317	383
12/15/20	1:28 PM	[redacted]	[redacted]	316	384
12/15/20	1:29 PM	[redacted]	[redacted]	315	386
12/15/20	1:30 PM	[redacted]	[redacted]	314	387
12/15/20	1:31 PM	[redacted]	[redacted]	314	388
Averages		[redacted]	[redacted]	**313.3**	**353.1**

Sterilization Run 3

gas charge ([redacted] lbs)					
Date	Time	Temp	Pressure	TE121 (CatOx Inlet)	TE124 (CatOx Outlet)
		degrees C	psia	degrees F	degrees F
12/15/20	5:09 PM	[redacted]		308	323
12/15/20	5:10 PM	[redacted]		308	323
12/15/20	5:11 PM	[redacted]		309	323
12/15/20	5:12 PM	[redacted]		308	323
12/15/20	5:13 PM	[redacted]		309	323
12/15/20	5:14 PM	[redacted]		309	324
12/15/20	5:15 PM	[redacted]		310	327
12/15/20	5:16 PM	[redacted]		312	333
12/15/20	5:17 PM	[redacted]		314	340
12/15/20	5:18 PM	[redacted]		313	347
12/15/20	5:19 PM	[redacted]		315	354
12/15/20	5:20 PM	[redacted]		316	360
12/15/20	5:21 PM	[redacted]		316	365
12/15/20	5:22 PM	[redacted]		316	370
12/15/20	5:23 PM	[redacted]		317	374
12/15/20	5:24 PM	[redacted]		316	378
12/15/20	5:25 PM	[redacted]		316	380
12/15/20	5:26 PM	[redacted]		315	383
12/15/20	5:27 PM	[redacted]		315	384
12/15/20	5:28 PM	[redacted]		315	385
12/15/20	5:29 PM	[redacted]		314	386
Averages		[redacted]		**312.9**	**352.6**

Date & Time	CatOx Inlet (temp °F) TE121	CatOx Outlet (temp °F) TE124
12/15/20 10:42 AM	310	338
12/15/20 10:43 AM	310	338
12/15/20 10:44 AM	311	338
12/15/20 10:45 AM	308	338
12/15/20 10:46 AM	307	337
12/15/20 10:47 AM	309	337
12/15/20 10:48 AM	309	336
12/15/20 10:49 AM	310	335
12/15/20 10:50 AM	309	334
12/15/20 10:51 AM	309	334
12/15/20 10:52 AM	309	334
12/15/20 10:53 AM	309	334
12/15/20 10:54 AM	309	334
12/15/20 10:55 AM	309	333
12/15/20 10:56 AM	309	333
12/15/20 10:57 AM	309	333
12/15/20 10:58 AM	308	333
12/15/20 10:59 AM	310	332
12/15/20 11:00 AM	311	332
12/15/20 11:01 AM	312	332
12/15/20 11:02 AM	311	332
12/15/20 11:03 AM	309	332
12/15/20 11:04 AM	308	333
12/15/20 11:05 AM	311	333
12/15/20 11:06 AM	311	333
12/15/20 11:07 AM	309	332
12/15/20 11:08 AM	308	332
12/15/20 11:09 AM	308	332
12/15/20 11:10 AM	310	332
12/15/20 11:11 AM	311	332
12/15/20 11:12 AM	311	331
12/15/20 11:13 AM	310	330
12/15/20 11:14 AM	309	330
12/15/20 11:15 AM	309	331
12/15/20 11:16 AM	309	331
12/15/20 11:17 AM	309	330
12/15/20 11:18 AM	309	330
12/15/20 11:19 AM	309	330
12/15/20 11:20 AM	309	329
12/15/20 11:21 AM	309	329
12/15/20 11:22 AM	309	329
12/15/20 11:23 AM	309	329
12/15/20 11:24 AM	310	328
12/15/20 11:25 AM	312	328

Process Data Aeration Run 1

Date & Time	CatOx Inlet (temp °F) TE121	CatOx Outlet (temp °F) TE124
12/15/20 11:26 AM	311	328
12/15/20 11:27 AM	311	328
12/15/20 11:28 AM	311	329
12/15/20 11:29 AM	311	329
12/15/20 11:30 AM	311	329
12/15/20 11:31 AM	311	329
12/15/20 11:32 AM	311	329
12/15/20 11:33 AM	311	329
12/15/20 11:34 AM	311	329
12/15/20 11:35 AM	311	329
12/15/20 11:36 AM	311	329
12/15/20 11:37 AM	311	329
12/15/20 11:38 AM	311	329
12/15/20 11:39 AM	308	329
12/15/20 11:40 AM	308	329
12/15/20 11:41 AM	309	329
Average	**309.7**	**331.6**

Date & Time	CatOx Inlet (temp °F) TE121	CatOx Outlet (temp °F) TE124
12/15/20 11:55 AM	310	326
12/15/20 11:56 AM	310	326
12/15/20 11:57 AM	310	325
12/15/20 11:58 AM	310	325
12/15/20 11:59 AM	310	325
12/15/20 12:00 PM	310	325
12/15/20 12:01 PM	310	325
12/15/20 12:02 PM	310	325
12/15/20 12:03 PM	309	325
12/15/20 12:04 PM	309	325
12/15/20 12:05 PM	309	324
12/15/20 12:06 PM	309	324
12/15/20 12:07 PM	309	324
12/15/20 12:08 PM	309	324
12/15/20 12:09 PM	309	324
12/15/20 12:10 PM	309	324
12/15/20 12:11 PM	309	324
12/15/20 12:12 PM	308	323
12/15/20 12:13 PM	308	323
12/15/20 12:14 PM	308	323
12/15/20 12:15 PM	308	323
12/15/20 12:16 PM	310	323
12/15/20 12:17 PM	312	323
12/15/20 12:18 PM	311	323
12/15/20 12:19 PM	312	323
12/15/20 12:20 PM	312	323
12/15/20 12:21 PM	310	323
12/15/20 12:22 PM	308	324
12/15/20 12:23 PM	310	324
12/15/20 12:24 PM	311	324
12/15/20 12:25 PM	310	324
12/15/20 12:26 PM	308	323
12/15/20 12:27 PM	308	322
12/15/20 12:28 PM	310	323
12/15/20 12:29 PM	311	323
12/15/20 12:30 PM	310	322
12/15/20 12:31 PM	309	322
12/15/20 12:32 PM	309	322
12/15/20 12:33 PM	309	322
12/15/20 12:34 PM	310	323
12/15/20 12:35 PM	310	322
12/15/20 12:36 PM	310	322
12/15/20 12:37 PM	310	322
12/15/20 12:38 PM	310	322

Process Data Aeration Run 2

Date & Time	CatOx Inlet (temp °F) TE121	CatOx Outlet (temp °F) TE124
12/15/20 12:39 PM	310	322
12/15/20 12:40 PM	310	322
12/15/20 12:41 PM	310	322
12/15/20 12:42 PM	311	322
12/15/20 12:43 PM	311	322
12/15/20 12:44 PM	311	323
12/15/20 12:45 PM	311	322
12/15/20 12:46 PM	311	322
12/15/20 12:47 PM	311	322
12/15/20 12:48 PM	311	322
12/15/20 12:49 PM	311	323
12/15/20 12:50 PM	310	323
12/15/20 12:51 PM	310	323
12/15/20 12:52 PM	308	323
12/15/20 12:53 PM	308	322
12/15/20 12:54 PM	310	322
Average	**309.8**	**323.2**

Date & Time	CatOx Inlet (temp °F) TE121	CatOx Outlet (temp °F) TE124
12/15/20 3:35 PM	312	334
12/15/20 3:36 PM	310	333
12/15/20 3:37 PM	307	333
12/15/20 3:38 PM	310	333
12/15/20 3:39 PM	311	333
12/15/20 3:40 PM	309	333
12/15/20 3:41 PM	308	333
12/15/20 3:42 PM	308	333
12/15/20 3:43 PM	309	333
12/15/20 3:44 PM	311	333
12/15/20 3:45 PM	312	332
12/15/20 3:46 PM	312	332
12/15/20 3:47 PM	309	332
12/15/20 3:48 PM	308	332
12/15/20 3:49 PM	309	333
12/15/20 3:50 PM	311	333
12/15/20 3:51 PM	312	332
12/15/20 3:52 PM	311	332
12/15/20 3:53 PM	309	331
12/15/20 3:54 PM	308	331
12/15/20 3:55 PM	310	331
12/15/20 3:56 PM	311	331
12/15/20 3:57 PM	311	331
12/15/20 3:58 PM	311	330
12/15/20 3:59 PM	311	330
12/15/20 4:00 PM	310	331
12/15/20 4:01 PM	310	331
12/15/20 4:02 PM	310	331
12/15/20 4:03 PM	310	330
12/15/20 4:04 PM	310	330
12/15/20 4:05 PM	310	330
12/15/20 4:06 PM	310	330
12/15/20 4:07 PM	310	329
12/15/20 4:08 PM	310	329
12/15/20 4:09 PM	310	328
12/15/20 4:10 PM	310	328
12/15/20 4:11 PM	310	328
12/15/20 4:12 PM	309	328
12/15/20 4:13 PM	309	328
12/15/20 4:14 PM	309	328
12/15/20 4:15 PM	308	327
12/15/20 4:16 PM	308	327
12/15/20 4:17 PM	308	327
12/15/20 4:18 PM	308	327

Process Data Aeration Run 3

Date & Time	CatOx Inlet (temp °F) TE121	CatOx Outlet (temp °F) TE124
12/15/20 4:19 PM	310	326
12/15/20 4:20 PM	311	326
12/15/20 4:21 PM	311	326
12/15/20 4:22 PM	312	326
12/15/20 4:23 PM	312	326
12/15/20 4:24 PM	310	327
12/15/20 4:25 PM	308	327
12/15/20 4:26 PM	308	327
12/15/20 4:27 PM	309	327
12/15/20 4:28 PM	311	327
12/15/20 4:29 PM	311	326
12/15/20 4:30 PM	310	326
12/15/20 4:31 PM	310	325
12/15/20 4:32 PM	309	326
12/15/20 4:33 PM	309	326
12/15/20 4:34 PM	309	326
Average	**309.8**	**329.5**